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Proposed Re-evaluation Decision

Rimsulfuron

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Overview

Proposed Re-evaluation Decision for Rimsulfuron

After a re-evaluation of the herbicide rimsulfuron, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing continued registration for the sale and use of products containing rimsulfuron in Canada.

An evaluation of available scientific information found that products containing rimsulfuron have value in the food and crop industry and do not present unacceptable risks to human health or the environment when used according to label directions. As a condition of the continued registration of rimsulfuron use on field corn, potatoes, tomatoes and lowbush blueberries, new risk reduction measures are proposed for inclusion on the labels of all rimsulfuron products. No additional data are being requested at this time.

The PMRA's pesticide re-evaluation program considers potential risks as well as the value of pesticide products to ensure they meet modern standards established to protect human health and the environment. Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, presents the details of the re-evaluation activities and program structure. Re-evaluation draws on data from registrants, published scientific reports, information from other regulatory agencies and any other relevant information available.

This proposal affects all end-use products containing rimsulfuron registered in Canada. Once the final re-evaluation decision is made, registrants will be instructed on how to address the new risk-reduction measures.

This Proposed Re-evaluation Decision is a consultation document[1] that summarizes the science evaluation for rimsulfuron and presents the reasons for the proposed re-evaluation decision. It also proposes additional risk-reduction measures to further protect human health and the environment.

The information is presented in two parts. The Overview describes the regulatory process and key points of the evaluation, while the Science Evaluation provides detailed technical information on the human health, environmental and value assessment of rimsulfuron.

The PMRA will accept written comments on this proposal up to 60 days from the date of publication of this document. Please forward all comments to Publications (please see contact information on the cover page of this document).

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*

What Does Health Canada Consider When Making a Re-evaluation Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions or proposed conditions of registration[2]. The Act also requires that products have value[3] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

To reach its decisions, the PMRA applies rigorous, modern hazard and risk assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in both humans (e.g. children) and organisms in the environment (e.g. those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties present when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the PMRA's website at www.pmra-arla.gc.ca.

Before making a re-evaluation decision on rimsulfuron, the PMRA will consider all comments received from the public in response to this consultation document[4]. The PMRA will then publish a Re-evaluation Decision document[5] on rimsulfuron, which will include the decision, the reasons for it, a summary of comments received on the proposed registration decision and the PMRA's response to these comments.

For more details on the information presented in this overview, please refer to the Science Evaluation section of this consultation document.

What Is Rimsulfuron?

Rimsulfuron is a selective systemic sulfonylurea herbicide. It is registered for use on several terrestrial food and feed crops including pre-emergent use on field corn (Eastern Canada only) as well as postemergent use on field corn (Eastern Canada and Manitoba), potatoes (Eastern Canada, irrigated potatoes in Western Canada and seed potatoes), tomatoes (transplanted processing and fresh market field) and lowbush blueberries (Eastern Canada only). Rimsulfuron

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2 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*

3 "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (a) efficacy; (b) effect on host organisms in connection with which it is intended to be used; and (c) health, safety and environmental benefits and social and economic impact".

4 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*

5 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*

may be used alone or in co-formulation with nicosulfuron to control quackgrass and annual grassy weeds as well as black bulrush, redroot pigweed (including triazine resistant) and lamb's-quarters (suppression only). One application per year is made by ground equipment only. Typical maximum application rates for rimsulfuron range from 12.5–15.0 g a.i./ha.

Health Considerations

Can Approved Uses of Rimsulfuron Affect Human Health?

Rimsulfuron is unlikely to affect your health when used according to label directions.

People could be exposed to rimsulfuron by consuming food and water, working as a mixer/loader/applicator or by entering treated sites. The PMRA considers two key factors when assessing health risks: the dose levels where no health effects occur and the dose levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (e.g. children and nursing mothers). Only those uses where exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels to which humans are normally exposed when using rimsulfuron products according to label directions.

An acute overexposure to rimsulfuron can produce a variety of symptoms in animals and humans. Symptoms may include weight loss, nasal secretions, ruffled fur and hair loss. Local effects of an acute dermal exposure may include slight erythema. Contact with the eye may cause corneal opacity, iritis, conjunctival redness and chemosis.

Additional toxic effects on the liver, kidney and testes, as well as effects noted in pregnant females (increased abortions and mortality), were observed in animals at very high doses only; therefore, they would not occur when rimsulfuron products are used according to label directions. Based on the weight of evidence, rimsulfuron is considered non-carcinogenic. A cancer risk assessment was not required.

Although there are no risks of concern based on current uses of rimsulfuron, some additional protective measures (personal protective equipment and improved work practices) have been proposed to update the product labels to the current standard and to further reduce the level of human exposure to rimsulfuron.

Residues in Water and Food

Dietary risks from food and water are not of concern.

Reference doses define levels to which an individual can be exposed over a single day (acute) or lifetime (chronic) and expect no adverse health effects. Generally, dietary exposure from food and water is acceptable if it is less than 100% of the acute reference dose or chronic reference dose (acceptable daily intake). An acceptable daily intake is an estimate of the level of daily exposure to a pesticide residue that, over a lifetime, is believed to have no significant harmful effects.

Human exposure to rimsulfuron was estimated from residues in treated crops and drinking water, including the most highly exposed subpopulation (e.g. children 1 to 6 years old). This aggregate exposure (i.e. to rimsulfuron from food and drinking water) represents less than 6% of the chronic reference dose.

The *Food and Drugs Act* prohibits the sale of adulterated food, that is, food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for the *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act.* Each MRL value defines the maximum concentration in parts per million (ppm) of a pesticide allowed in/on certain foods. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Rimsulfuron is currently registered in Canada for use on lowbush blueberries, field corn, potatoes and tomatoes. MRLs for rimsulfuron are currently specified for blueberry and tomatoes or processed foods derived from these foods. No specific MRLs have been established for corn and potatoes. Where no specific MRL has been established, a default MRL of 0.1 ppm applies, which means that pesticide residues in a food commodity must not exceed 0.1 ppm. The proposed amendments to the default MRL for rimsulfuron can be found in the Science Evaluation Section 8.1.2 of this consultation document.

Risks in Residential and Other Non-Occupational Environments

Residential and other non-occupational risks are not of concern.

Rimsulfuron is not registered for use in any residential areas. Therefore, no residential or other non-occupational risks are expected.

Occupational Risks From Handling Rimsulfuron

Occupational risks are not of concern.

Based on both the precautions and directions for use on the original product labels reviewed for this re-evaluation, and also considering the use of appropriate protective equipment, the risk estimates associated with mixing, loading and applying activities meet current standards for all the scenarios and are not of concern. The proposed personal protection equipment include long pants, long-sleeved shirt and chemical-resistant gloves.

Postapplication risks are not of concern.

Occupational postapplication risk assessments consider exposures to workers re-entering treated sites in agriculture. Based on the precautions and directions for use on the original product labels reviewed for this re-evaluation, and also considering proposed protective measures (revised re-entry interval), postapplication non-cancer risk estimates to re-entry workers performing high exposure activities (scouting) meet current standards and are not of concern.

Environmental Considerations

What Happens When Rimsulfuron is Introduced into the Environment?

Rimsulfuron poses a potential risk to certain terrestrial and aquatic plants, therefore, additional risk-reduction measures need to be observed.

When rimsulfuron is applied for control of weeds in crops, some of it finds its way into soil and water. However, the chemical is not expected to persist as it is rapidly broken down by soil microbes and by chemical reaction in water. The breakdown chemical products that are formed persist for a longer period of time than rimsulfuron. Both rimsulfuron and its breakdown products are mobile and hence can move freely in soil. Water runoff on the soil surface can move the residues into nearby bodies of water, such as ponds and rivers. Water monitoring of these bodies of water have generally revealed residues at concentrations below levels of concern. To reduce the potential for leaching and runoff, it is important that additional risk reduction measures are observed.

When rimsulfuron is used for weed control in crops, there is a potential that sensitive plant species on land and in water may be exposed to the chemical as a result of the spray drifting or runoff. Some of these species are sensitive to the chemical and would be adversely affected. To minimize the potential exposure, strips of land (buffer zones) between the agricultural field and the non-target terrestrial or aquatic areas will be left unsprayed. The width of these buffer zones will be specified on the product label. Rimsulfuron poses negligible risk to wild birds and mammals, bees and other arthropods as well as to aquatic organisms like fish, amphibians and invertebrates because concentrations in the environment are not expected to be harmful. Rimsulfuron's major

transformation products pose a negligible risk to earthworms and terrestrial plants, as well as to aquatic organisms such as fish, aquatic invertebrates, amphibians and aquatic plants.

Value Considerations

What is the Value of Rimsulfuron?

Rimsulfuron controls quackgrass and many annual grassy weeds in several crops at a low application rate.

Rimsulfuron reduces a portion of the economic losses caused by weeds estimated at $94.4 million in the early 1990s for field corn, potatoes, tomatoes and blueberries. Rimsulfuron (co-formulated with nicosulfuron) is the only herbicide registered for the control of black bulrush in lowbush blueberries. Compared to alternative non-sulfonylurea postemergent herbicides, rimsulfuron has greater flexibility in application timing when used on field corn, has no or fewer restrictions on crop variety and soil type for use on tomatoes and potatoes. Although rimsulfuron plays a role in mitigating resistance development in weeds to other herbicide groups and may be used to control triazine-resistant redroot pigweed, consideration has to be given to resistance management as more weed species are reported to be resistant to herbicides that inhibit acetolactate synthase (such as rimsulfuron) than to herbicides having other modes of action.

Measures to Minimize Risk

Labels of registered pesticide product labels include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law. As a result of the re-evaluation of rimsulfuron, the PMRA is proposing further risk-reduction measures for product labels.

Human Health

- To protect mixer/loader/applicators: additional protective equipment
- To protect workers re-entering treated sites: a restricted-entry interval
- To protect workers using wettable granular formulation: additional precautionary statements and directions for use
- To avoid drift to areas of human habitation or areas of human activity: precautionary statements

Environment

- To protect non-target terrestrial and aquatic plants: adding precautionary statements and directions for use, as well as buffer zones for terrestrial and aquatic plants
- To reduce the potential runoff of rimsulfuron to adjacent aquatic habitats: statements cautioning use on sites with characteristics that may enhance runoff when heavy rain is forecasted
- To reduce the potential for rimsulfuron and its residues to leach to ground water: statements cautioning use in areas with permeable soils and/or shallow water tables.

Next Steps

Before making a re-evaluation decision on rimsulfuron, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will then publish a Re-evaluation Decision document, which will include the decision, the reasons for it, a summary of comments received on the proposed decision and the PMRA's response to these comments.

Other Information

When the re-evaluation decision is made, the PMRA will publish an Evaluation Report on rimsulfuron in the context of this re-evaluation decision (based on the Science Evaluation section of this consultation document). In addition, the test data on which the decision is based will be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

Science Evaluation

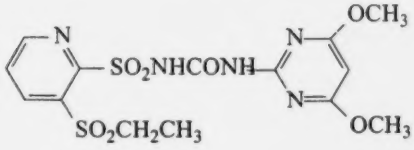
1.0 Introduction

Rimsulfuron is a selective systemic herbicide. It belongs to the sulfonylurea chemical family and is classified as a Group 2 herbicide. The herbicidal activity of rimsulfuron is due to the inhibition of the plant enzyme acetolactate synthase (ALS), also called acetohydroxyacid synthase (AHAS).

Following the re-evaluation announcement for rimsulfuron, E.I. du Pont Canada Company, the registrant of the technical grade active ingredient (TGAI) and primary data provider in Canada, indicated it would continue to support all uses included on the label of Commercial Class end-use products. There are no Domestic Class products containing rimsulfuron registered in Canada.

2.0 The Technical Grade Active Ingredient, Its Properties and Uses

2.1 Identity of the Technical Grade Active Ingredient

Common name	Rimsulfuron
Function	Herbicide
Chemical family	Sulfonylurea
Chemical name	
1. International Union of Pure and Applied Chemistry (IUPAC)	1-(4,6-dimethoxypyrimidin-2-yl)-3-(3-ethylsulfonyl-2-pyridylsulfonyl)urea
2. Chemical Abstracts Service (CAS)	N-[[(4,6-dimethoxy-2-pyrimidinyl)amino]carbonyl]-3-(ethylsulfonyl)-2-pyridinesulfonamide
CAS Registry Number	122931-48-0
Molecular formula	$C_{14}H_{17}N_5O_7S_2$
Molecular weight	431.4
Structural formula	

PCP Registration Number:	23517
Purity:	99% NS (limits: 96.0–100.0%)
Basic Manufacturer:	Dupont Agricultural Products Caribe Ltd Manati Plant, Manati, Puerto Rico

Based on the manufacturing process, the product is not expected to contain impurities of human health or environmental concern as identified in Regulatory Directive DIR98-04, *Chemistry Requirements for the Registration of a Technical Grade of Active Ingredient or an Integrated System Product*, Section 2.13.4 or Toxic Substances Management Policy (TSMP) Track 1 substances as identified in Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*, Appendix II.

2.2 Physical and Chemical Properties of the Technical Grade Active Ingredient

Property	Result
Vapour pressure	1.5×10^{-3} mPa
Ultraviolet–visible spectrum	No UV absorption observed at λ >300 nm
Solubility in water at 25°C	<10 mg/L (unbuffered) 7.3 g/L (buffered, pH 7)
n-Octanol–water partition coefficient (K_{ow}) at 25°C	pH $\log K_{ow}$ 5 0.288 7 -1.47
Dissociation constant (pKa)	pKa = 4.0

2.3 Description of Registered Rimsulfuron Uses

Appendix I lists all rimsulfuron products registered under the authority of the *Pest Control Products Act*, including one technical grade active ingredient, two manufacturing concentrates, and six Commercial Class end-use products. Four of the Commercial Class end-use products contain rimsulfuron alone and the remaining two rimsulfuron products are co-formulated with nicosulfuron.

Appendix II lists all the uses for which rimsulfuron is presently registered. All uses were supported by the registrant at the time of initiation of re-evaluation and were, therefore, considered in the health and environmental risk assessments. Also presented is whether any of the uses were added through the PMRA minor use program. While currently supported by the registrant, the data supporting these minor uses were originally generated by a user group.

Uses of rimsulfuron belong to the following use site categories: terrestrial food crops and terrestrial feed crops. The crops specifically include field corn, lowbush blueberries, potatoes and tomatoes.

3.0 Impact on Human and Animal Health

Toxicology studies in laboratory animals describe potential health effects resulting from various levels of exposure to a chemical and identify dose levels where no effects are observed. Unless there is evidence to the contrary, it is assumed that effects observed in animals are relevant to humans and that humans are more sensitive to effects of a chemical than the most sensitive animal species. The health effects noted here were observed in animals at dose levels at least 100-fold (often much higher) above levels to which humans are normally exposed through use of products containing this chemical.

3.1 Toxicological Summary

The toxicology database supporting rimsulfuron is primarily based on studies from the technical registrant. In laboratory animals, rimsulfuron is of low acute toxicity by the oral, dermal, and inhalation routes of exposure, non-irritating to rabbit skin, moderately irritating to rabbit eyes, and a non-sensitizer in Guinea pigs. Signs of acute toxicity induced by very high doses of rimsulfuron are weight loss, ruffled fur, nasal discharge and hair loss.

After oral exposure, rimsulfuron was rapidly absorbed from the gastrointestinal tract, more than 80% of the administered dose was excreted within the first 24 hours and more than 90% within 72 hours. Accumulation within tissues was minimal, with 58–72% of the administered activity recovered from the urine, and 21–35% recovered from the feces. The main component was the parent compound. The major metabolic pathway was a sulfonylurea bridge contraction followed by oxidation and hydroxylation reactions. A number of minor metabolites were found in the urine and in the feces.

In short- and long-term studies, the major effects were a reduction in body weight or body-weight gain and changes in the liver. In subchronic mouse, rat and dog studies reduced body-weight gains occurred with an increase in liver weight. An increase in the incidence of hepatocellular hypertrophy was also noted in the rat. Additionally, in the 90-day mouse study there was an increase in several hematological parameters (RBC, Hgb, HCT, eosinophils) and in the dog studies (90-day and 1-year) there was an increase in testicular atrophy/degeneration of the seminiferous tubules, an increase in kidney weight, and an increase in levels of serum alkaline phosphatase, and serum cholesterol.

In the mouse oncogenicity study, in addition to reduced body weight and body-weight gain and increased relative liver weight, there was an increase in the relative weights of the kidney, testes and heart. At the highest dose tested, there were testicular effects (deformation, degeneration of the testicular artery) and increased incidences of liver masses and hepatocellular adenomas. In the combined chronic/oncogenicity rat study, in addition to reduced body weight and body-weight gain, and increased relative and absolute liver weights, other effects included diffuse and focal fatty changes in the liver, a slightly increased incidence of centrilobular

hepatocellular hypertrophy, and an increased relative kidney weight. The incidence of lymphosarcomas and histiocytic sarcomas was increased at interim sacrifice, but overall the increased incidences at the high dose were not statistically significant and were within normal ranges of in-house historical data for the latter part of the study. All genotoxicity studies were negative. Rimsulfuron is considered non-carcinogenic.

In a rat reproduction study and a rabbit developmental study, reductions in body weight/body-weight gain and food consumption were noted. In rabbits, maternally toxic effects including increased mortality and increased abortions (late) were noted at the highest dose (1500 mg/kg bw/day). Reproductive and offspring sensitivities were not observed.

Reference doses have been set based on the NOAEL for the most sensitive indicator of toxicity, namely decreases in body weight and body-weight gain, increases in organ (liver, kidney) weight and testicular effects in dogs. Reference doses incorporate uncertainty factors to account for extrapolating between laboratory animals and humans.

The toxicology profile of rimsulfuron and endpoints used in the risk assessment of rimsulfuron are summarized in Appendix III and IV.

3.2 Occupational and Non-Occupational Risk Assessment

Occupational and non-occupational risk is estimated by comparing potential exposures with the most relevant endpoint from toxicology studies to calculate a margin of exposure (MOE). This is compared to a target MOE incorporating safety factors protective of the most sensitive subpopulation. If the calculated MOE is less than the target MOE, it does not necessarily mean that exposure will result in adverse effects. However, MOEs less than the target MOE require mitigation measures to reduce risk.

3.2.1 Toxicological Endpoints

To estimate the risk from short-, intermediate- and long-term oral, dermal and inhalation exposure, an oral NOAEL of 9.6 mg/kg bw/day from the combined results of a 90-day and a 1-year dog study was used. The NOAEL was based on decreased body weight and body-weight gain, increased absolute and relative liver and kidney weights, increased incidence of seminiferous tubule degeneration and increased number of spermatid giant cells in the epididymides, at a LOAEL of 81.8 or 193 mg/kg bw/day. A target MOE of 100 is based on the standard uncertainty factors of 10 for interspecies extrapolation and 10 for intraspecies variability.

The PMRA does not consider rimsulfuron to be a possible human carcinogen based on a weight-of-evidence approach.

Dermal Absorption
All dermal exposure scenarios included in this assessment were considered to be of short- or intermediate-term in duration. As the toxicological endpoint for these scenarios is based on an oral NOAEL, and no dermal absorption study was available, the PMRA used a dermal absorption factor of 100% for a tier one assessment.

3.2.2 Occupational Exposure and Risk Assessment

Workers can be exposed to rimsulfuron through mixing, loading or applying the herbicide during normal use, and when re-entering a treated site to conduct activities such as scouting and/or handling treated crops.

Mixer/Loader/Applicator Exposure and Risk Assessment
There are potential exposures to mixers, loaders and applicators. The following supported uses were assessed:

- Mixing and loading wettable granules for application to terrestrial field crops;
- Mixing and loading wettable granules in water-soluble packaging (WSP) for application to terrestrial field crops;
- Applying wettable granules as sprays to terrestrial field crops by groundboom;
- Mixing, loading and applying wettable granules in WSP to lowbush blueberries by low pressure handwand and backpack.

Occupational handlers of rimsulfuron include farmers and custom agricultural applicators who mix, load and apply the herbicide. As only one application is permitted per season, the duration of exposure for farmers is short-term (1 to 30 days). In the case of custom applicators applying rimsulfuron to several fields per season, the duration of exposure may be considered intermediate-term (1 to 6 months). Exposure for all crop scenarios is predominantly dermal, with inhalation accounting for a minor component of overall exposure.

The PMRA estimated handler exposure based on the following level of personal protective equipment (PPE):

Baseline PPE: Long pants, long-sleeved shirt and chemical-resistant gloves (unless specified otherwise, i.e. for groundboom application, chemical-resistant gloves are not included in the scenario).

Mixer/loader/applicator exposure estimates are based on the best available data at this time. The assessment might be refined with product-specific exposure data, biological monitoring data, or dermal absorption data.

No chemical specific exposure studies were available for use in the re-evaluation of rimsulfuron. Thus, appropriate dermal and inhalation exposures were estimated using the Pesticide Handlers Exposure Database (PHED), Version 1.1. PHED is a compilation of generic mixer/loader and applicator passive dosimetry data with associated software which facilitates the generation of scenario-specific exposure estimates based on formulation type, application equipment, mix/load systems and level of personal protective equipment. In some cases, PHED did not contain appropriate data sets to estimate exposure to workers wearing additional PPE and/or using engineering controls. Surrogate data for wettable granules in WSP were not available in PHED, therefore closed mixing and loading data for wettable granules were used.

For some scenarios (e.g. hand-held equipment), estimating exposure from mixing, loading and applying wettable granules in WSP was not possible using PHED. In these situations, exposure units from mix/load/apply with open pour liquid for low pressure handwand and backpack were used.

PHED unit exposures coupled with information on the amount of rimsulfuron handled per day was used to estimate handler exposure. The amount handled per day is based upon the maximum label application rate and default assumptions on the crop area which can reasonably be treated in one day.

Calculated MOEs exceed the target MOE for all exposure scenarios and are summarized in Table 1 of Appendix V.

Postapplication Worker Exposure and Risk Assessment

The postapplication occupational risk assessment considered exposures to workers entering treated agricultural sites to conduct activities involving foliar contact. Based on the rimsulfuron use pattern, there is potential for short-term (1 to 30 days) postapplication exposure to rimsulfuron residues for workers.

Chemical-specific dislodgeable foliar residue (DFR) data and activity specific transfer coefficients (TC) were used to estimate postapplication exposure resulting from contact with treated foliage at various times after application. DFR data include the amount of residue that can be dislodged or transferred from a surface, such as the leaves of a plant. A TC is a factor that relates worker exposure to dislodgeable residues. TCs are specific to a given crop and activity combination (e.g. hand harvesting apples, scouting late season cotton) and reflect standard agricultural work clothing worn by adult workers. Postapplication exposure activities include scouting, thinning, hand pruning, hand harvesting, hand weeding, staking, tying, training, irrigation and detasseling.

For workers entering a treated site, restricted-entry intervals (REIs) are calculated to determine the minimum length of time required before people can safely re-enter. An REI is the duration of time that must elapse before residues decline to a level where performance of a specific activity results in exposures above the target MOE (i.e. >100 for short-term exposure scenarios).

Although rimsulfuron is applied to agricultural areas including terrestrial feed and food crops, no relevant DFR studies were available. As a result, a conservative default value of 20% of the application rate with a 10% dissipation per day was used.

The postapplication risk estimates include a number of conservative inputs, such as the assumption that workers are exposed to residues following the maximum application rate.

Calculated MOEs exceed the target MOE on day 0, and proposed REIs are 12 hours. Postapplication exposure calculations for each use site are summarized in Table 2 of Appendix V.

3.2.3 Residential Exposure and Risk Assessment

There are no domestic class products registered for rimsulfuron in Canada; therefore, a residential risk assessment was not required.

3.3 Dietary Risk Assessment

In a dietary exposure assessment, the PMRA determines how much of a pesticide residue, including residues in milk and meat, may be ingested with the daily diet. Exposure to rimsulfuron from potentially treated imports is also included in the assessment. These dietary assessments are age specific and incorporate the different eating habits of the population at various stages of life. For example, the assessments take into account differences in children's eating patterns, such as food preferences and the greater consumption of food relative to their body weight when compared to adults. Dietary risk is then determined by the combination of the exposure and the toxicity assessments. High toxicity may not indicate high risk if the exposure is low. Similarly, there may be risk from a pesticide with low toxicity if the exposure is high.

The PMRA considers limiting use of a pesticide when risk exceeds 100% of the reference dose. The PMRA's Science Policy Note SPN2003-03, *Assessing Exposure from Pesticides, A User's Guide*, presents detailed acute and chronic risk assessments procedures.

Residue estimates used in the dietary risk assessment (DRA) may be conservatively based on the maximum residue limits (MRL) or the field trial data representing the residues that may remain on food after treatment at the maximum label rate. Surveillance data representative of the national food supply may also be used to derive a more accurate estimate of residues that may remain on food when it is purchased. These include the Canadian Food Inspection Agency's National Chemical Residue Monitoring Program and the United States Department of Agriculture Pesticide Data Program (PDP).

Chronic dietary risk assessments were conducted using the Dietary Exposure Evaluation Model (DEEM–FCID™, Version 2.03), which uses updated food consumption data from the United States Department of Agriculture's Continuing Surveys of Food Intakes by Individuals, 1994–1996 and 1998.

For more information on dietary risk estimates or residue chemistry information used in the dietary assessment, see Appendix VI and VII.

3.3.1 Determination of Acute Reference Dose

An acute (1 day) reference dose (ARfD) was not calculated since there was not an acute endpoint of concern.

3.3.2 Determination of Acceptable Daily Intake

The acceptable daily intake (ADI) is the dose that an individual can be exposed to over the course of a lifetime and expect no adverse health effects. The ADI selected for rimsulfuron was based on a NOAEL of 9.6 mg/kg bw/day from the combined results of a 90-day and a 1-year study in dogs. The endpoint selected was based on decreased body weight and body-weight gain, increased absolute and relative liver and kidney weights, and an increased incidence of seminiferous tubule degeneration and an increased number of spermatid giant cells in the epididymides at a LOAEL of 81.8 or 193 mg/kg bw/day. An overall uncertainty factor of 100 was required to account for interspecies extrapolation (10-fold) and intraspecies variability (10-fold), resulting in an ADI of 0.096 mg/kg bw/day (9.6 mg/kg bw/day ÷ 100). This value was considered protective of all populations, including infants and children, and females of childbearing age (13–49 years).

3.3.3 Chronic Dietary Exposure and Risk Assessment

The chronic dietary risk was calculated by using the average consumption of different foods and water considering average residue values. This expected intake of residues from food and water was then compared to the ADI.

The chronic potential daily intake for both food and water accounted for less than 6% of the ADI for all subpopulations and is, therefore, not of concern.

3.3.4 Cancer Potency Factor

A cancer risk assessment was not conducted since the rimsulfuron database did not suggest any carcinogenic potential in mice or rats.

3.3.5 Carcinogenic Dietary Exposure and Risk Assessment

A cancer risk assessment was not conducted since the rimsulfuron database did not suggest any carcinogenic potential in mice or rats.

3.4 Exposure From Drinking Water

3.4.1 Concentrations in Drinking Water

Rimsulfuron residues in potential drinking water sources were estimated using computer simulation models. The chronic estimated drinking water concentration value used in the exposure model is 0.04 parts per billion (ppb).

3.4.2 Drinking Water Exposure and Risk Assessment

Drinking water estimates were incorporated directly in the exposure model. For more information, refer to Section 3.5, Aggregate Risk Assessment.

3.5 Aggregate Risk Assessment

Aggregate exposure is the total exposure to a single pesticide that may occur from food, drinking water, residential and other non-occupational sources as well as from all known or plausible exposure routes (oral, dermal and inhalation).

As residential use of rimsulfuron is not permitted, aggregate exposure is from dietary and drinking water exposures only (see Sections 3.3 and 3.4). Chronic aggregate (food and water) exposures were less than the respective reference doses. Therefore, aggregate exposure from all relevant sources is not considered a health concern.

4.0 Impact on the Environment

4.1 Fate and Behaviour in the Environment

Based on its physical-chemical properties (Section 2.2), rimsulfuron is soluble in water, is not likely to volatilize from moist soil or water surfaces under field conditions, and is not likely to bioaccumulate in organisms. Environmental fate data for rimsulfuron are summarized in Table 1 of Appendix X. Rimsulfuron is relatively labile and dissipates from soil and aquatic systems by hydrolysis and biotransformation. At cooler temperatures the dissipation of rimsulfuron is slower in all environmental media. Phototransformation is not an important route of transformation for rimsulfuron, however, it may assist the breakdown of the major transformation products associated with rimsulfuron. The major transformation products IN-70941, IN-70942, and IN-E9260 are generally more persistent than rimsulfuron. IN-70942 and IN-E9260 are stable to hydrolysis, although IN-E9260 was not detected as a major transformation product in the water or sediment phases of aquatic test systems. Water/sediment studies demonstrated that the majority of the applied radioactivity (~21 to ~ 93%) is preferentially associated with the sediment phase by study termination (89–100 days), and that much of that applied radioactivity is bound (up to 42%) suggesting that rimsulfuron and its transformation products are less available to aquatic organisms.

Laboratory studies on adsorption/desorption, thin layer chromatography, and soil column leaching indicate that rimsulfuron and its transformation products, IN-70941, IN-70942,

IN-E9260, have a potential to be mobile in a variety of soils. Laboratory studies indicate that rimsulfuron and its transformation products, IN-70941, IN-70942 and IN-E9260 have the potential to leach. Rimsulfuron and its transformation products met all criteria identifying them as leachers. Suitable terrestrial field studies conducted in Canada, or in Canadian equivalent ecoregions, were not available to assess the leaching potential of rimsulfuron and its transformation products in the field. Terrestrial field studies conducted in the US and Europe indicate varying degrees of leaching. The extent of rimsulfuron leaching is related to the time of application, amount of rainfall and soil characteristics. The potential for leaching is especially prominent in non-acidic soils because of increased solubility and decreased adsorption. Leaching of rimsulfuron and its transformation products in terrestrial field studies ranged from a soil depth of 7.6 cm to a depth of 30 cm. Evidence of leaching may be hampered by the fact that soils were only sampled to depths of 7.6 cm or 30 cm depending on the study. Canadian water monitoring data have shown detections in surface water at concentrations of less than 1.0 µg a.i./L, while at present, there are no monitoring data for groundwater (Appendix VIII).

The proposed transformation pathway is the bridge-contraction reaction to form IN-70941 and IN-70942, followed by the cleavage of the sulfonylurea linkage to form IN-E9260, IN-T5831 and IN-J290 (Appendix IX, Diagram 1).

4.2 Effects on Non-target Species

The environmental risk assessment determines the potential for adverse ecological effects in each environmental compartment by comparing the ratio of the estimated environmental exposure to the ecotoxicological effect. The estimated environmental exposure concentration (EEC) is the initial or cumulative concentration of pesticide in the various sources of food, water and soil to which the organism is exposed. EECs are calculated by different methods for each media (food, water or soil). If multiple applications of pesticide are used, cumulative EECs are determined by using the time taken to decline to 50% of the original application (DT_{50}) using the minimum time interval between applications for each environmental media.

The risk assessment is initially conducted using a screening-level scenario which assumes maximum exposure (EEC) and the most sensitive toxicological endpoint for the organism of interest. This assumes direct application or overspray to the environmental media (food, water, soil) to which the organism is exposed. This is the most conservative scenario and generally does not reflect the exposure to which an organism would be subject to when the pesticide is applied according to the label instructions. Risk to the environment is calculated as a risk quotient (RQ) which is the ratio between the environmental exposure and the toxicological endpoint for the organism (i.e. RQ = EEC/toxicological endpoint). The threshold or level of concern for potentially harmful effects to an organism is an RQ value of 1 where the exposure exactly equals the toxicological endpoint. RQ values greater than or equal to 1 are considered to equal or exceed the level of concern which may result in potentially harmful effects to the organism. RQ values less than 1 indicate negligible risk to the organism because they are below the threshold for harmful effects. In the latter case, no further assessment is carried out. If the RQ is greater than or equal to 1, the level of concern, then a refinement of the risk assessment is carried out to assess the level of concern using scenarios which are a better approximation of exposure or toxicological effects and less conservative. Refinements can include (i) exposure from the

fraction of pesticide which drifts onto non-target habitats, instead of assuming 100% overspray, and (ii) exposure from the amount of pesticide predicted in runoff, instead of assuming direct overspray to water (i.e. 100% exposure). The refinements may also consider different toxicity endpoints or a percentile of a species sensitivity distribution rather than the most sensitive endpoint. They may also consider the results of a mesocosm study using several species rather than the toxicity from a single species. Further refinements to the risk assessment may consider the use of monitoring data collected in the field rather than EECs generated by a model.

4.2.1 Effects on Terrestrial Organisms

A risk assessment of rimsulfuron to terrestrial organisms was based upon an evaluation of toxicity data on rimsulfuron to earthworms (acute contact), bees (acute oral and chronic), two species of birds (acute oral, dietary, and chronic), two species of mammals (acute oral, dietary, and chronic), and a variety of terrestrial plants (emergence). Toxicity data on formulated products were also available for earthworms (acute contact), bees (acute oral and contact), beneficial invertebrates (acute contact), birds (acute oral and dietary), and terrestrial plants (vegetative vigor). As well, toxicity data for the transformation products IN-70941, IN-70942, and IN-E9260 were available for earthworm (reproduction) and terrestrial plants (emergence and vegetative vigour). A summary of terrestrial toxicity data for rimsulfuron, as technical active or in formulation, and its transformation products are presented in Table 2 of Appendix X. For the assessment of risk, toxicity endpoints chosen from the most sensitive species were used as surrogates for the wide range of species that can be potentially exposed following treatment with rimsulfuron (Table 3a, 3b, and 3c of Appendix X).

Rimsulfuron and its transformation products demonstrated no adverse toxicological effects on terrestrial invertebrates. This was confirmed in a field study in which no treatment related effects were observed in macro-fauna collected from a rimsulfuron treated field (40 g a.i./ha) using pitfall traps and soil cores over a 17-month period. As well, rimsulfuron demonstrated no treatment related adverse toxicological effects to birds or mammals on an acute oral, dietary and reproductive basis. Plant emergence and vegetative vigor studies conducted with ten plant species (four monocot and six dicot) indicated that, although the seeds of most plant species emerged successfully, plants did not follow normal growth patterns. Studies conducted with rimsulfuron transformation products indicated that IN-70941, IN-70942, and IN-E9260 did not affect emergence or growth of any of the seventeen plant species tested (11 monocot and six dicot).

The risk assessment was conducted using data for the earthworm, honeybee, bobwhite quail, mallard duck, and rat. In the case of terrestrial plants, the most sensitive monocot species was sorghum *(Sorghum bicolor)*, while the most sensitive dicot was canola (*Brassica napus*).

The screening level risk assessment indicated that exposure to rimsulfuron and its transformation products do not pose a risk to terrestrial invertebrates, wild birds and mammals at the current registered label rates. As well, risk to terrestrial plants from exposure to the transformation products IN-70941, IN-70942, and IN-E9260 is not expected as the no observed effects concentration (NOEC) for each product was 400 g/ha, well above the currently registered label rates for rimsulfuron. A risk assessment of the end-use products was not conducted as the end-use products used in the terrestrial toxicology studies are not currently registered for use in Canada and, with the information provided, it was not possible to determine if the products used are similar to those products registered for use in Canada. Table 3a and 3b of Appendix X summarizes the risk assessment from rimsulfuron and its transformation products to terrestrial organisms.

The screening level risk assessment concluded that rimsulfuron poses a potential risk to non-target terrestrial plants. The level of concern (LOC) was exceeded by as much as 187 times. A refinement of the risk assessment was conducted taking into consideration the concentrations of rimsulfuron that could be present in terrestrial habitat directly adjacent to the application field through drift of spray. Spray drift data for a medium American Society of Agricultural Engineers (ASAE) droplet size, as are generally used in ground boom applications of herbicides, indicate that the maximum amount of spray that will drift one metre down wind from the point of application during spraying is 6%. Using this percent drift, the off-site EECs for rimsulfuron were calculated. Based on this method of refinement, rimsulfuron poses a reduced risk to non-target terrestrial plants directly adjacent to the application field. Exceedance of the LOC was reduced to 11 times from 187 times. Incident reports documenting adverse effects to cropped species (corn, peas, and soybean), as well as an ash tree, support the conclusions of the risk assessment. Buffer zones will be required to reduce the risk of rimsulfuron to non-target terrestrial plants. The transformation products IN-70941, IN-70942, and IN-E9260 are not expected to be in the environment at concentrations that would result in a risk to terrestrial non-target plants. Table 4 of Appendix X summarizes the refined risk assessment from rimsulfuron to non-target terrestrial plants.

4.2.2 Effects on Aquatic Organisms

Risk to aquatic organisms, acute and chronic, is based on an evaluation of toxicity data on rimsulfuron for nine freshwater species (two invertebrates, three fish, three algae, and one vascular plant) and four estuarine/marine species (two invertebrates, one fish, and one algae). Acute and chronic toxicity data on formulated products for freshwater invertebrates, fish, algae, and vascular plants were also available. As well, acute toxicity data on the transformation products IN-70941, IN-70942, and IN-E9260 were available for freshwater invertebrates, fish, algae, and vascular plants. A summary of aquatic toxicity data for rimsulfuron is presented in Table 2 of Appendix X. For the assessment of risk, toxicity endpoints chosen from the most sensitive species were used as surrogates for the wide range of species that can be potentially exposed following treatment with rimsulfuron (Table 5a and 5b of Appendix X).

Rimsulfuron and its transformation products are not toxic to freshwater or estuarine/marine invertebrates or fish on an acute bases, or to freshwater fish and invertebrates on a chronic bases. Rimsulfuron significantly affected biomass and cell density of freshwater algae and freshwater and marine/estuarine diatoms. However, data indicate that there is a potential for algae to recover from acute exposure to rimsulfuron. Rimsulfuron significantly affected frond density and biomass of duckweed, however, in contrast to the algae data, duckweed may not be able to recover after acute exposure to rimsulfuron. The transformation products IN-70941, IN-70942, and IN-E9260 did not adversely affect algae or duckweed at the maximum concentrations tested.

According to acute toxicity, the most sensitive freshwater invertebrate, fish, algae and vascular plant species were *Daphnia carinata*, common carp, green algae and duckweed, respectively. Acute toxicity data were available for only one species of estuarine/marine invertebrate (mysid shrimp), fish (sheepshead minnow), and aquatic plant (diatom). Chronic toxicity data were available for only one species of freshwater invertebrate (*Daphnia magna*) and fish (rainbow trout), while no chronic toxicity data were available for estuarine/marine species.

The screening level risk assessment indicated that rimsulfuron and its transformation products do not pose a risk to freshwater or estuarine/marine invertebrates, fish, algae and amphibians (based on surrogate data from fish studies). A risk assessment of the end-use products was not conducted as the end-use products used in the aquatic toxicology studies are not currently registered for use in Canada and, with the information provided, it was not possible to determine if the products used are similar to those products registered for use in Canada. Table 5a and 5b of Appendix X summarizes the risk assessment from rimsulfuron and its transformation products to aquatic organisms.

The screening level risk assessment concluded that rimsulfuron poses a potential risk to non-target aquatic vascular plants. The LOC was exceeded by 3.7 times. A refinement of the risk assessment was conducted taking into consideration the concentrations of rimsulfuron that could be present in non-target water bodies directly adjacent to the application field through drift of spray (using the same methods as for the refined terrestrial risk assessment) and through runoff (as modelled by PRZM/EXAMS). The refined risk assessment reduced the exceedance of the LOC to less then one from spray drift and to 1.5 times from runoff. To mitigate risk to aquatic vascular plants from rimsulfuron, a buffer zone and precautionary label statements will be required on the label. Table 6 of Appendix X summarizes the refined risk assessment to non-target aquatic plants from rimsulfuron spray drift and runoff.

Although surface water monitoring data are available for rimsulfuron (Appendix VIII), these data are limited and were not used in the aquatic risk assessment because of the following source of uncertainties: 1) sampling was conducted at regular time intervals and may not have coincided with runoff events in the watershed; 2) rimsulfuron use information from the areas surrounding where the samples were collected were not available.

5.0 Value

5.1 Commercial Class Products

All rimsulfuron uses are supported by the registrant. There are no risk concerns for any of the registered uses. Consequently, no further information regarding alternatives to the use of rimsulfuron is considered.

5.2 Domestic Class Products

There are no Domestic Class products containing rimsulfuron registered in Canada.

5.3 Value of Rimsulfuron

Quackgrass is one of the most troublesome and difficult to control weeds. A recent survey estimated that about 56% of Canadian farmland has quackgrass present. It can reduce corn yields by as much as 25 to 85%. Rimsulfuron is one of few herbicides which effectively control quackgrass in field corn.

In Canada, the estimated average annual losses caused by weeds in the early 1990s were $54.4 million in field corn, $32.5 million in potatoes, $4.7 million in tomatoes, and $2.8 million in blueberry. Rimsulfuron was reported to be widely used in field corn, potatoes and tomatoes to prevent and reduce a portion of the economic losses caused by weeds. In addition, rimsulfuron (co-formulated with nicosulfuron) is the only herbicide registered for the control of black bulrush in lowbush blueberries.

Rimsulfuron has no, or fewer, restrictions than the alternative postemergent grass and broadleaf herbicides for use on tomato and potato. Rimsulfuron may be used on both fresh market field tomatoes and transplanted tomatoes grown for processing while the registered alternatives may only be used on fresh market field tomatoes. When used on potatoes, rimsulfuron has no variety restrictions while its alternative has several variety restrictions (e.g. it cannot be used on red skinned varieties, Shepody or Atlantic potatoes, or potatoes grown for the early market). Similarly, soil restrictions associated with the use of rimsulfuron are fewer than the alternatives.

When used in field corn, the application window of rimsulfuron is wider (1–8-leaf stage for corn) than that of alternative non-sulfonylurea postemergent grass herbicides (spike to 2- or 3-leaf stage for corn).

The development of herbicide resistance in weeds associated with the use of rimsulfuron must be considered. Due to the widespread and frequent use of acetolactate synthase inhibiting (Group 2) herbicides such as rimsulfuron, and lack of rotation with herbicides with other modes of action, more resistant weed biotypes have been documented in Canada with Group 2 herbicides than with any other herbicide group, including 12 broadleaf weeds (cleavers, chickweed, hemp-nettle, kochia, lamb's-quarters, giant ragweed, ball mustard, wild mustard, redroot pigweed, Russian thistle, spiny annual sowthistle, and stinkweed) and two grassy weeds (green foxtail and wild oats). Nevertheless, rimsulfuron still plays a role in managing and/or mitigating resistance

development in weeds to other herbicide groups. For instance, rimsulfuron is registered for the control of triazine resistant redroot pigweed.

6.0 Toxic Substances Management Policy Considerations

The management of toxic substances is guided by the federal government's *Toxic Substances Management Policy* (TSMP), which puts forward a preventive and precautionary approach to deal with substances that enter the environment and could harm the environment or human health. The policy provides decision makers with direction and sets out a science-based management framework to ensure that federal programs are consistent with its objectives. One of the key management objectives is virtual elimination from the environment of toxic substances that result predominantly from human activity and that are persistent and bioaccumulative. These substances are referred to in the policy as Track 1 substances.

During the review process, rimsulfuron was assessed in accordance with the PMRA Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*. Substances associated with the use of rimsulfuron were also considered, including major transformation products formed in the environment, microcontaminants in the technical product and formulants in the end-use products. The PMRA has reached the following conclusions:

- The *n*-octanol–water partition coefficient (log K_{ow}) of rimsulfuron is -1.47, which is below the TSMP Track 1 cut-off criterion for log $K_{ow} \geq 5.0$. As well, rimsulfuron does not meet the criteria for persistence as its half-life values in water (1–11 days) and soil (18–40 days) are below the TSMP Track 1 cut-off criteria for water (≥182 days), sediment (≥182 days) and soil (≥182 days).

- The major transformation products IN-70941 and IN-70942 do not meet the criteria for TSMP Track 1 as the half-life values for persistence in water (12–28 and 27–107 days, respectively) are below the TSMP Track 1 cut-off criterion for water of ≥182 days. Although the transformation product IN-E9260 meets the criterion for persistence in soil (252–969 days, above the TSMP Track 1 cut-off criteria in soil of ≥182 days), is hydrolytically stable, and aquatic biotransformation studies are not available, it does not meet the criterion for toxicity as studies indicate that IN-E9260 is not toxic to terrestrial invertebrates and aquatic organisms (freshwater invertebrates, fish and aquatic plants).

Therefore, the use of rimsulfuron is not expected to result in the entry of Track 1 substances into the environment.

6.1 Formulant Issues

Formulant issues are being addressed through the PMRA formulant initiatives and Regulatory Directive DIR2006-02, *Formulant Policy and Implementation Guidance Document* published on 31 May 2006.

7.0 Summary

7.1 Human Health and Safety

7.1.1 Occupational Risk

The occupational application and postapplication risks are acceptable for the exposure scenarios involving the use of rimsulfuron. The calculated margins of exposure for application and postapplication occupational exposures are all above the Agency's target assuming that workers wear baseline personal protective equipment.

7.1.2 Dietary Risk from Food

Chronic dietary risk assessments demonstrate that there were no dietary concerns for any population subgroup in Canada, including infants, children, teenagers, adults and seniors. In addition, no dietary concerns were evident for nursing or pregnant females or based on gender in general.

7.1.3 Dietary Risk from Drinking Water

The potential for the contamination of drinking water with rimsulfuron is expected to be negligible. There are no drinking water concerns for any population subgroup in Canada, including infants, children, teenagers, adults and seniors.

7.1.4 Residential Risk

Rimsulfuron is not registered for use in any residential areas so a residential risk assessment was not required.

7.1.5 Aggregate Risk

Aggregate exposure and risk are from dietary and drinking water exposures only. This aggregate exposure (i.e. to rimsulfuron from food and drinking water) represents less than 6% of the chronic reference dose and was not considered a health risk.

7.2 Environmental Risk

Rimsulfuron is non-persistent in most soils and water systems, although its transformation products are more persistent than the parent compound. There is a potential that under appropriate environmental conditions, rimsulfuron and its transformation products may leach to groundwater and/or runoff to surface water. The risk assessment of rimsulfuron indicate that adverse effects on non-target terrestrial and aquatic plants are expected.

7.3 Value

Rimsulfuron controls quackgrass and many annual grassy weeds in several important crops at a low application rate.

Rimsulfuron reduces a portion of the economic losses caused by weeds (estimated at $94.4 million in the early 1990s) for field corn, potatoes, tomatoes and blueberries. Rimsulfuron (co-formulated with nicosulfuron) is the only herbicide registered for the control of black bulrush in lowbush blueberries. Compared to alternative non-sulfonylurea postemergent herbicides, rimsulfuron has greater flexibility in application timing when used on field corn, has no or fewer restrictions on crop variety and soil type for use on tomatoes and potatoes. Although rimsulfuron plays a role in mitigating resistance development in weeds to other herbicide groups and may be used to control triazine resistant redroot pigweed, consideration has to be given to resistance management as more weed species are reported to be resistant to herbicides that inhibit acetolactate synthase (such as rimsulfuron) than to herbicides having other modes of action.

8.0 Proposed Regulatory Decision

The PMRA is proposing that rimsulfuron is acceptable for continued registration with the implementation of the proposed risk-reduction measures. These measures are required to further protect human health and environment. As a condition of the continued registration of rimsulfuron uses, new risk reduction measures must be included on the labels of all products. No additional data are being requested at this time.

8.1 Proposed Regulatory Actions Related to Human Health

The PMRA has determined that the dietary and drinking water risks, worker risks during mixing, loading and application are acceptable for all uses provided that the mitigation measures listed in Appendix XI are implemented.

8.1.1 Residue Definition for Risk Assessment and Enforcement

Division 15, Table II, of the Food and Drug Regulations currently identifies rimsulfuron (*N*-[[(4,6-dimethoxy-2-pyrimidinyl)amino]carbonyl]-3-(ethylsulfonyl) as the residue for risk assessment and enforcement. This residue definition is consistent with that of the USEPA.

8.1.2 Maximum Residue Limits for Rimsulfuron in Food

In general, when the re-evaluation of a pesticide has been completed, the PMRA intends to update Canadian maximum residue limits and to remove MRLs that are no longer supported.

As shown in Table 8.1.2, the Food and Drug Regulations specify MRLs for rimsulfuron residues in blueberries and tomatoes. Residues in all other agricultural commodities, including corn and potatoes approved for treatment in Canada but without a specified MRL, must not exceed the general MRL of 0.1 ppm.

Where no specific MRL for a pest control product has been established in the Food and Drug Regulations, subsection B.15.002(1) applies. This requires that residues do not exceed 0.1 ppm and has been considered a general MRL for enforcement purposes. Currently, residues of rimsulfuron in all agricultural commodities including corn and potatoes approved for treatment in Canada are regulated by subsection B.15.002(1). However, changes to this general MRL may be implemented in the future, as indicated in Discussion Document DIS2006-01, *Revocation of 0.1 ppm as a General Maximum Residue Limit for Food Pesticide Residues [Regulation B.15.002(1)]*.

Extrapolation of available residue data for corn and potatoes following good agricultural practices (GAP), as described by the current product labels, indicated that residues would not exceed the limit of quantitation of the analytical method of 0.05 ppm. If and when the general MRL is revoked, a transition strategy will be established to allow permanent MRLs to be set for corn and potatoes.

Table 8.1.2 Rimsulfuron MRLs for Commodities Approved in Canada

Commodity	MRL (ppm)
Blueberry	0.05
Corn	0.1*
Potato	0.1*
Tomato	0.05

* By virtue of subsection B.15.002(1) of the Food and Drug Regulations, the maximum residue limit of foods for which MRLs have not specifically been established is 0.1 ppm.

For supplemental MRL information regarding the International situation and trade implications, refer to Appendix XII.

8.2 Proposed Regulatory Action Related to Environment

The PMRA has determined that to reduce the effects of rimsulfuron in the environment, mitigation in the form of precautionary label statements and terrestrial buffer zones listed in Appendix XI are required.

List of Abbreviations

°C	degree(s) Celsius
a.i.	active ingredient
ADI	acceptable daily intake
AHAS	acetohydroxyacid synthase
ALS	acetolactate synthase
ARfD	acute reference dose
ASAE	American Society of Agricultural Engineers
atm	atmospheres
bw	body weight
CFIA	Canadian Food Inspection Agency
cm	centimetre(s)
DEEM®	Dietary Exposure Evaluation Model
DER	Data Evaluation Report
DFR	dislodgeable foliar residue
DNA	deoxyribonucleic acid
DPY	rimsulfuron
DT_{50}	dissipation time to 50% (the dose required to observe a 50% decline in the test population)
DWLOC	drinking water level of comparison
EC_{25}	exposure concentration to 25% (a concentration causing 25% adverse effects in the test population
EC_{50}	exposure concentration to 50% (a concentration causing 50% adverse effects in the test population
EChE	erythrocyte cholinesterase
EEC	expected environmental concentration
EP	end-use product
EXAMS	Exposure Analysis Modeling System
F/T/P	Canadian Federal, Provincial, and Territorial Committee
F_0	parental animals
F_1	first filial generation
g	gram(s)
GAP	good agricultural practice
GC-FPD	Gas Chromatography-Flame Photometric Detector
GC-MSD	Gas Chromatography-Mass Selective detector
GC-NPD	Gas Chromatography-Nitrogen Phosphorous Detector
h	hour(s)
ha	hectare(s)
Hg	mercury
IRED	Interim Reregistration Eligibility Decision (USEPA Document)
K_d	adsorption coefficient
kg	kilogram(s)
K_{oc}	organic carbon partition coefficient
K_{ow}	octanol–water partition coefficient
L	litre(s)

LC_{50}	lethal concentration to 50% (a concentration causing 50% mortality in the test population
LD_{50}	lethal dose to 50% (a dose causing 50% mortality in the test population)
LOAEL	lowest observed adverse effect level
LOC	level of concern
LOD	limit of detection
LOEC	lowest observed effect concentration
m	metre(s)
m/sec	metre(s) per second
m^3	metre(s) cubed
mg	milligram(s)
µg	microgram(s)
mL	millilitre(s)
mm	millimetre(s)
MOE	margin of exposure
mv	millivolt(s)
MWHC	maximum water holding capacity
nd	no detection
nm	nanometre(s)
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
OC	organic carbon
OM	organic matter
PChE	plasma cholinesterase
PCP	Pest Control Product
PDP	Pesticide Data Program (United States data)
pH	-log10 hydrogen ion concentration
PHED	Pesticide Handlers Exposure Database
PHI	preharvest interval
PMRA	Pest Management Regulatory Agency
ppb	parts per billion
PPE	personal protective equipment
ppm	parts per million
PRZM	Pesticide Root Zone Model
PSI	pre-slaughter interval
Q_1^*	cancer potency factor
REI	restricted-entry interval
Rf	retardation factor in chromatography
RQ	risk quotient
TC	transfer coefficient
TGAI	technical grade active ingredient
TP	transformation product
TPM	triophanate-methyl
TSMP	Toxic Substances Management Policy
URMULE	User Requested Minor Use Label Expansion
US	United States of America
USEPA	United States Environmental Protection Agency

USGS NAWQA	United States Geological Survey National Water-Quality Assessment Program
wk	week

Appendix I Registered Rimsulfuron Products as of 11 July 2006

Registration Number	Marketing Class[1]	Registrant	Product Name	Formulation Type	Guarantee (%)[2]	
					DPY	NIO
23517	T	E.I. du Pont Canada Company	Rimsulfuron Technical Herbicide	Solid	99	-
23518	C		Elim EP Herbicide 25% Dry Flowable	Wettable granules	25	-
23521	M		Rimsulfuron 25DF (For manufacturing)		25	-
23589	C		Prism Herbicide 25% Dry Flowable		25	-
23983	C		Prism Herbicide 25% Dry Flowable		25	-
24800	C		Elim EP Herbicide 25% Dry Flowable		25	-
24682	C		Ultim Herbicide 37.4% Dry Flowable		18.7	18.7
24736	C		Ultim Herbicide 75% Dry Flowable		37.5	37.5
26676	M		Ultim 75 DF MUP		37.5	37.5

1 T = Technical grade active ingredient; M = Manufacturing concentrate; C = Commercial.

2 DPY = rimsulfuron; NIO = nicosulfuron; - = not included.

Note: Discontinued products or products with a submission for discontinuation are not included.

Appendix II Registered Uses of Rimsulfuron as of 11 July 2006[1]

Use Site Category	Sites		Weeds[2]	Maximum Application Rate (g a.i./ha)	Supported Use?[3]
13, 14 Terrestrial feed crops and terrestrial food crops	Field corn	Eastern Canada	A	15	Y
			B + quackgrass		
			B		
			C	12.6 plus nicosulfuron at 12.6 (co-formulation)	Y
			Long-spined sandbur		M
		Manitoba	C		M
14 Terrestrial food crops	Lowbush blueberries	Eastern Canada	Black bulrush	12.6 plus nicosulfuron at 12.6 (co-formulation)	M
	Potatoes	Eastern Canada	D	15	Y
		Seed potatoes			Y
		Irrigated potatoes in western Canada			M
	Tomatoes (transplanted processing tomatoes and fresh market field tomatoes)		E plus hairy nightshade		M

1 The formulation type for all supported end-use products is wettable granules. Application is made once per year by ground equipment only. No aerial application is allowed for any uses. Information on application equipment and the number of applications is based on both label use information and information provided by the registrant under DACO 5.2. Uses of tank mix products including the prepackaged tank mixes are not presented.

2 All weeds listed below are treated postemergence, except A which are treated pre-emergence:

A = Barnyard grass, green foxtail, large (hairy) crabgrass (suppression), and yellow foxtail (suppression);

B = Barnyard grass, fall panicum, green foxtail, old witchgrass, yellow foxtail (suppression), redroot pigweed (including triazine resistant), and lamb's-quarters (suppression);

C = Barnyard grass, fall panicum, green foxtail, proso millet, quackgrass, redroot pigweed (including triazine resistant), yellow foxtail (suppression), and old witchgrass; and

D = Barnyard grass, fall panicum, green foxtail, witchgrass, quackgrass, yellow foxtail, redroot pigweed, and lamb's-quarters (suppression).

3 Y = Use is currently registered and supported by the registrant.

M = Use was added as a User Requested Minor Use Label Expansion and is supported by the registrant.

Appendix III Toxicology Profile for Rimsulfuron

NOTE: Effects noted below are known or assumed to occur in both sexes unless otherwise specified.

Study/Species/ # of Animals per Group	NOAEL (mg/kg bw/day)	Results/Effects
Metabolism/Toxicokinetic Studies		
Metabolism of ^{14}C-rimsulfuron (^{14}C-pyridine or ^{14}C-pyrimidine)—CD rats		Absorption: rapid absorption (based on the rate of excretion) Distribution:- minimal residual tissue activity (0.053–0.385% of the administered dose) with highest levels in whole blood, liver, skin and kidneys Metabolism:- The major metabolic pathway was a sulphonylurea bridge contraction, followed by oxidation and hydroxylation reactions. The cleavage of the sulfonylurea bridge occurred to only a limited extent. The metabolic pathway did not vary by sex, dose level or dosing regime. Main urinary component was parent compound representing 42–55% of the administered dose. Other identified urinary metabolites were: IN-70941 or N-(4,6-dimethoxy-2-pyrimidinyl)-N-((3-ethylsulphonyl)-2-pyridinyl) urea (3.9–5.7%); IN-70942 or N-((3-ethylsulphonyl)-2-pyridinyl)-4,6-dimethoxy-2-pyrimidineamine) (0.0–0.8%); desmethyl IN-70942 (3.0–7.9%); and IN-E9260 or 3-(ethylsulphonyl)-2-pyridinesulphonamide (7.2–9.6%). In fecal samples from repeat dose females and single high dose animals the predominant component was the parent compound (5.5–16.0%); at the single low dose and repeat dose males, the parent, metabolite P4 and metabolite IN-E9260 were in approximately equal amounts. The identified metabolites in the feces were: desmethyl IN-70942 (0.4–1.6%); P4 or OH-desmethyl IN-70942 (5.9–9.4%); and IN-E9260 (4.9–6.9%). Excretion:- The majority of the administered dose was excreted in 24 hr (>80%) in all groups. By 72 hours over 90% of the dose had been excreted via the urine and feces. Urine (72 hours): 58.1–67.0% (♂) and 62.0–72.4% (♀). Faeces (72 hours): 27.5–35.3% (♂) and 20.5–32.6% (♀) - sex, dosing regime, dose level, label position essentially had no effect on the excretion pattern.

Study/Species/ # of Animals per Group	NOAEL (mg/kg bw/day)	Results/Effects
Acute Toxicity Studies		
Acute oral toxicity—mouse		LD_{50} >5000 mg/kg bw **LOW TOXICITY**
Acute oral toxicity—rat		LD_{50} >5000 mg/kg bw Signs : ruffled fur (1/sex on day 2) with sporadic ↓bw (♀) **LOW TOXICITY**
Acute dermal toxicity—rabbit		LD_{50} >2000 mg/kg bw Signs: occasional ↓bw **LOW TOXICITY**
Acute inhalation toxicity—rat		LD_{50} >5.4 mg/L Signs: red ocular and nasal discharge, hair loss (2♀ at end of study), ↓bw (day following exposure - some animals) **LOW TOXICITY**
Eye irritation—rabbit		Slight corneal opacity, moderate iritis and conjunctival irritation consisting of mild chemosis and slight to moderate redness in 6/6, minimal ocular discharge in 1/6; no corneal injury, all treated eyes normal by day 3. Mean scores: 31.3 (1hr); 2.3 (24 hr); 1.0 (48 hr); 0 (72 hr) **MODERATELY IRRITATING**
Dermal irritation—rabbit		**NON-IRRITATING**
Dermal sensitization—Guinea pig		**NON-SENSITIZER**
Subchronic Toxicity Studies		
90-day oral (feeding) —mouse	228.0/ ≥1575.0 (♂/♀)	1219/1575 mg/kg bw/day: ↑RBC (♂), ↑Hgb (♂), ↑HCT (♂), ↑eosinophils (♂) (after 37 and 99 days)
90-day oral (feeding)—rat	3.35	≥3.35/4.11 mg/kg bw/day: ↓mean food efficiency ≥102/120 mg/kg bw/day: ↓bw (♂-6%;♀-5.9%), ↓bw gain (♂-7.4%;♀-8%) ≥495/615 mg/kg bw/day:↓food consumption (♂), ↑liver wt. [absol.(♂ only) and rel.(♂/♀)], ↑incidence of hepatocellular hypertrophy 1311/1622 mg/kg bw/day: ↓food consumption, ↑liver wt. (absol. and rel.), ↑urine volume (♀), ↓urine osmolality (♀)
90-day oral (feeding) —Beagle dog	9.63	≥193/189 mg/kg bw/day:↑urine volume (♀), ↓urine osmolality (♀), ↑liver wt. (absol. and rel.), ↑kidney wt. [absol.(♂ only) and rel.(♂ only)], testicular atrophy/degeneration of seminiferous tubules (1/4; 2/4 next dose) 793/677 mg/kg bw/day: ↓bw (♂-13.6%;♀-18.1%), ↓bw gain, ↓food consumption (♀), ↓food efficiency, ↑serum ALP, ↓serum albumin, ↑serum cholesterol (♂), ↑urine volume, ↓urine osmolality, ↑rel. kidney wt.

Study/Species/ # of Animals per Group	NOAEL (mg/kg bw/day)	Results/Effects
1-year oral (feeding) —Beagle dog	1.6	≥81.8/86.5 mg/kg bw/day: ↓bw gain (♀ - 29.3%), ↓bw (♀ - 10.8%), ↑serum ALP (♀), ↑serum cholesterol (♀), ↑absol. liver wt.(♂), ↑absol. kidney wt.(♂), ↑seminiferous tubule degeneration, ↑# spermatid giant cells in the epididymides 342.4/358.5 mg/kg bw/day: ↑serum ALP, ↑serum cholesterol, ↑urine volume, ↓urine specific gravity and osmolality, ↑liver wt. (absol. and rel.), ↑rel kidney wt., ocular opacities, ↑hyperplasia of the tracheal mucosa
Chronic Toxicity/Oncogenicity Studies		
18-month feeding study —mouse	357	1147/1541 mg/kg bw/day: ↓bw (♂-6.8%;♀-5.8%), ↓bw gain (♂-14.3%;♀-15.3%), ↓food efficiency, ↑incidence of cataracts (♀), ↓absol. kidney weight (♂), ↑rel. liver weight, ↑rel testes weight, ↑rel. kidney and heart weight (♀), ↑incidence of liver masses and hepatocellular adenomas (but ↓hepatocellular carcinomas) (♂)*, ↑ incidence of discoloured and deformed testes, ↑ incidence and severity of degenerative changes in the testicular artery and the tunica albuginea *The increased incidence of adenomas at the high dose was not significant according to Fisher's exact test. The total number of hepatic tumours (benign and malignant) and the total number of animals affected in the high-dose group were only slightly higher than seen in the control group, and close to the range of values reported for the in-house historical control groups. **Not carcinogenic**
Two-year feeding study— rat	11.8/163(♂/♀)	≥121/163 mg/kg bw/day: ↓bw(♂ - 11.3%), ↓bw gain(♂ - 13.8%), diffuse and focal fatty changes in liver (♂) 414/569 mg/kg bw/day: ↓survival (♂)*, ↑rel. liver wt., ↑absol. liver wt (at 24 months - ♀ only), ↑rel. kidney wt (at 12 months - ♂ only), slight ↑incidence of centrilobular hepatocellular hypertrophy, diffuse and focal fatty changes in liver (♂), bile duct hyperplasia, ↑incidence of lymphosarcoma and histiocytic sarcoma (♂)** *Increased mortality was seen in the high-dose group from study week 14 to study week 79, however, overall, the number of ♂'s surviving from study initiation through to terminal sacrifice was comparable between the control and high-dose group (26.9% vs 25%) **Although the incidences at the high dose were greater than control values, they were not statistically significant. The incidence of these tumours exceeded historical control data only up to the interim kill (i.e., they were within normal ranges compared to in-house historical data for the second year of a two-year study). These tumours occur spontaneously in aging rats. **Not carcinogenic**

Study/Species/ # of Animals per Group	NOAEL (mg/kg bw/day)	Results/Effects
Reproductive and Developmental Toxicity Studies		
Two-generation reproduction feeding study—rat	Parental/ Offspring: 165 Reproductive: ≥830	Parental: ≥165-264 mg/kg bw/day: ↓food intake (F_1♂- premating; P_1♀- gestation) 830–1316 mg/kg bw/day: ↓bw [F_1♂(12%); F_1♀- premating (4.4% -non-sig.)], ↓bw gains [F_1♂ (13.5%); F_1♀- premating (9.9% -non-sig.); P_1♂- premating (6.8%)], ↓food efficiency (F_1♂) Reproductive: no adverse treatment-related effects on reproductive parameters Offspring: 830–1316 mg/kg bw/day: ↓pup bw (F_2 litters - days 7 and 14 of lactation) no signs of increased sensitivity
Developmental study (gavage)—rat	Maternal: 2000 Developmental: ≥6000	Maternal: 6000 mg/kg bw/day: ↓bw gain (22.5% - during dosing), ↓food consumption (during dosing), discoloured (tan) feces Developmental: 6000 mg/kg bw/day:↑ # fetuses with skeletal variations (increased incidence of partial ossification of the skull and ribs indicative of delayed development, and an increased incidence of wavy ribs). However, these findings were not considered significant on a litter basis. no signs of increased sensitivity 6000 mg/kg bw/day is considered to be an excessively high dose (maximum guideline is 1000 mg/kg bw/day) and is, therefore, not very relevant to human risk assessment. **No evidence of teratogenicity**
Developmental study (gavage)—rabbit	Maternal/ Developmental: 170	Maternal: 500 mg/kg bw/day: ↑mortality (½0), ↑abortions (2/18 - 11.1%; 1 at 24 days, 1 at 26 and 28 days, i.e., abortion begins day26, ends day 28) [abortions (2) and mortality (1) are within historical controls], ↓food consumption (during dosing) 1500 mg/kg bw/day: ↑mortality (15/20), ↑abortions (3/16 - 18.8%; 2 at 22 days, and 1 at 23 and 24 days, i.e., abortion begins day 23, ends day 24), ↓bw*, ↓food consumption* *(due to the high mortality rate in the high dose group, the limited data available were excluded from the study analysis; however, examination of individual animal data indicated that mean bw and mean food intake were severely reduced in this group during the dosing period) Developmental: 500 mg/kg bw/day: ↑abortions (2/18 - 11.1%; 1 at 24 days, 1 at 26 and 28 days) 1500 mg/kg bw/day: ↑abortions (3/16 - 18.8%; 2 at 22 days, and 1 at 23 and 24 days) no signs of increased sensitivity **No evidence of teratogenicity**

Study/Species/ # of Animals per Group	NOAEL (mg/kg bw/day)	Results/Effects
Genotoxicity Studies		
Ames reverse mutation test —*Salmonella typhimurium* TA1535, TA97, TA98, TA100	**Negative**	
Ames reverse mutation test —*Salmonella typhimurium* TA1535, TA97, TA98, TA100	**Negative**	
In vivo bone marrow micronucleus assay—CD-1 mice	**Negative**	
In vitro gene mutation assay—CHO/HGPRT cells	**Negative**	
In vitro unscheduled DNA synthesis assay—rat primary hepatocytes	**Negative**	
In vitro chromosome aberration assay—human lymphocytes	**Negative**	

Appendix IV Toxicology Endpoints for Health Risk Assessment for Rimsulfuron

Exposure Scenario	Dose (mg/kg bw/day)	Endpoint	Study	UF/SF or MOE[a]
Acute dietary	An acute reference dose was not calculated since there was not an endpoint of concern			
Chronic dietary	NOAEL = 9.6	Decreased body weight and body-weight gain, increased absolute and relative liver and kidney weights, increased incidence of seminiferous tubule degeneration, and increased number of spermatid giant cells in the epididymides	90-day and 1-year feeding studies—dog	100
	ADI = 0.096 mg/kg bw/day			
Short[b]-, intermediate[c]- and long[d]-term oral, dermal and inhalation[e]	NOAEL = 9.6	Decreased body weight and body-weight gain, increased absolute and relative liver and kidney weights, increased incidence of seminiferous tubule degeneration, and increased number of spermatid giant cells in the epididymides	90-day and 1-year feeding studies—dog	100
Cancer	non-carcinogenic			

[a] UF/SF refers to total of uncertainty and/or safety factors for dietary assessments, MOE refers to desired margin of exposure for occupational or residential assessments

[b] Duration of exposure is 1–30 days

[c] Duration of exposure is 1–6 months

[d] Duration of exposure is >6 months

[e] Because an oral NOAEL was selected, an inhalation absorption factor of 100% (default value) should be used in route-to-route extrapolation

Appendix V Summary of Occupational Risk Estimates for Rimsulfuron

Table 1 Route Specific MOEs for Mixers/Loaders/Applicators of Products Containing Rimsulfuron

Baseline PPE : long-sleeved shirt, long pants and chemical-resistant gloves (open cab, no gloves for groundboom application)									
Crop	Method of Application	Formulation[a]	Application Rate[b]	Area Treated per Day[c]	Daily Exposure (µg/kg/day)		Margins of Exposure[f] Target = 100		
					Dermal	Inhalation No Respirator	Dermal[d]	Inhalation[e] No Respirator	Combined[g] No Respirator
Field Corn	Groundboom	WG	0.015 kg a.i./ha	Farmer : 100 ha	4.22	0.04	2300	230 000	2300
				Custom : 300 ha	12.65	0.13	760	75 000	750
		WG in WSP		Farmer : 100 ha	1.06	0.02	9000	420 000	8900
				Custom : 300 ha	3.17	0.07	3000	140 000	3000
Potatoes	Groundboom	WG	0.015 kg a.i./ha	Farmer : 100 ha	4.22	0.04	2300	230 000	2300
				Custom : 300 ha	12.65	0.13	760	75 000	750
Tomatoes	Groundboom	WG	0.015 kg a.i./ha	30 ha	1.26	0.013	7600	750 000	7500
Lowbush blueberries	Groundboom	WG in WSP	0.0126 kg a.i./ha	30 ha	0.27	0.0057	36 000	1 700 000	35 000
	Low pressure handwand		0.000016 kg a.i./L	150 L	0.03	0.0015	300 000	6 200 000	280 000
	Backpack			150 L	0.19	0.0021	51 000	4 500 000	51 000

[a] Formulations are defined as follows: WG = wettable granules (open mixing and loading); WG in WSP = wettable granules in water-soluble packaging (closed mixing and loading).

[b] Maximum label rate.

[c] Default tier 1 area treated per day values.

[d] Dermal MOE = dermal NOAEL / dermal exposure. The short- and intermediate-term dermal NOAEL is 9.6 mg/kg bw/day. Dermal exposure = (dermal unit exposure value × area treated per day × use rate × DA) / BW. (DA = dermal absorption of 100%; BW = body weight of 70 kg)

[e] Inhalation MOE = inhalation NOAEL / inhalation exposure. The short- and intermediate-term inhalation NOAEL is 9.6 mg/kg bw/day. Inhalation exposure = (Inhalation unit exposure value × area treated per day × use rate)/ BW. (BW = body weight of 70 kg)

[f] Target MOE of 100 for short- and intermediate-term exposure scenarios.

[g] Combined MOE = $\frac{1}{(1/MOE_{Dermal}) + (1/MOE_{Inhalation})}$

Table 2 Post-Application Exposure Estimates for Re-entry into Fields Treated with Rimsulfuron

Use-site Category 13 and 14 : Terrestrial Feed and Food Crops							
Crop and Rate (kg a.i./ha)	Number of Applications per Year	Activity	Transfer Coefficient[a] (cm^2/hour)	Peak DFR[b] (µg/cm^2) (at day 0)	Systemic Exposure[c] (µg/kg bw/day)	MOE[d] (Target = 100)	Proposed REI[e] (hours)
Field Corn[f] Rate: 0.015	1	Scouting	400	0.03	1.37	7000	12
		Irrigation, scouting	1000	0.03	3.43	2800	12
		Detasseling	17 000	0.03	58.29	170	12
Lowbush Blueberries Rate: 0.0126	1	Irrigation, thinning, hand pruning, scouting, hand weeding	400	0.0252	1.15	8300	12
		Hand harvesting, hand pruning	1500	0.0252	4.32	2200	12
Tomatoes Rate: 0.015	1	Irrigation, scouting, hand weeding, thinning	500	0.03	1.71	5600	12
		Irrigation, scouting, hand pruning, staking, tying	700	0.03	2.4	4000	12
		Hand harvesting, hand pruning, staking, thinning, training, tying	1000	0.03	3.43	2800	12
Potatoes Rate: 0.015	1	Hand weeding, irrigation, scouting	300	0.03	1.03	9300	12
		Irrigation and scouting	1500	0.03	5.14	1900	12

a Transfer coefficients are from the Science Advisory Council for Exposure, Policy No. 003.1 (USEPA, 2000) and any amendments thereof.

b DFR calculations are based on a default peak residue value of 20% of the application rate and 10% dissipation rate per day. Based on one application per season.

c Systemic exposure = DFR × TC × 8 hrs × DA / 70 kg. (TC = transfer coefficient; DA = dermal absorption of 100%)

d Based on worker short-term NOAEL of 9.6 mg/kg bw/day and target MOE of 100. MOE = NOAEL/Exposure

e REI = Restricted-entry interval

f Based on the early seasonal application of rimsulfuron, a hand harvesting/detasseling assessment was not required.

Appendix VI Dietary (Food and water) Exposure and Risk Estimates for Rimsulfuron

Rimsulfuron		
Chronic exposure ADI = 0.096 mg/kg bw/day		
Population	**Dietary (food and water) Exposure mg/kg bw/day**	**% ADI**
Canadian Population (total)	0.001327	1.4%
All infants (< 1 year)	0.001943	2.0%
Children 1–2 yrs	0.005209	5.4%
Children 3–5 yrs	0.003789	3.9%
Children 6–12 yrs	0.002361	2.5%
Youth 13–19 yrs	0.001292	1.3%
Adults 20–49 yrs	0.000876	0.9%
Adults 50+ yrs	0.000746	0.8%
Females 13–49 yrs	0.000861	0.9%
Reference dose	ADI	0.096 mg/kg bw/day

Appendix VII Food Residue Chemistry Summary

1.1 Metabolism

The PMRA concluded that the residue chemistry database for rimsulfuron is largely complete. Nature and magnitude of the residue in plants and livestock are adequately understood. Conclusions from the European Food Safety Authority (2005), the Environment Protection Agency (1998) and the United Kingdom Pesticides Safety Directorate (1995) are consistent with the PMRA's conclusion.

1.1.1 Plant Metabolism

The PMRA has reviewed rimsulfuron metabolism studies conducted on corn, potato and tomato and concluded that the qualitative and quantitative metabolic fate, transposition and disposition of rimsulfuron have been adequately demonstrated. Studies were conducted using radiolabelled forms (pyridine and pyrimidine rings) in order to investigate the fate of the 2 moieties of the compound. None of the metabolites formed is found to be of particular concern. As the results of three metabolism studies on dissimilar crops indicated a similar metabolic route in the three crops, additional metabolism studies would not be required. However, due to significant amounts (30–55% TRR) of two metabolites found in tomato foliage, the PMRA may require additional metabolism and residue studies if registrant wishes to propose new uses on treated foliage crops (e.g. leafy vegetables). The first step in tomato foliage is the contraction of the sulfonyl urea bridge (PHI of 0 to 60 days; <0.003 ppm to 0.48 ppm). This metabolite may further degrade by demethylation of the pyrimidine ring and the loss of the carboxamide moiety (PHI of 0 to 60 days; <0.003 ppm to 0.17 ppm).

Although plants were treated using exaggerated rates at approximately 3.5 to 5 times the maximum total annual use rate, total radioactive residues in edible plant parts (corn grains, potato tubers and tomatoes) as well as in fractions intended for animal consumption were not detected (always below the LOQ of 0.02 mg parent equivalent/kg). Since finite ^{14}C-residues (>0.02 ppm) were not detected in the mature plants, the metabolic fate of rimsulfuron was elucidated using the ^{14}C-residues recovered from the immature foliage. Based on the identification of the metabolites, the metabolism of rimsulfuron in plants proceeds primarily by two pathways:

- contraction of the sulfonylurea bridge; and,
- cleavage of the sulfonylurea bridge which undergo further secondary metabolism/conjugation to yield highly polar and non polar components.

1.1.2 Livestock Metabolism

The PMRA has reviewed rimsulfuron metabolism studies conducting on lactating goat and laying hens with orally administered rimsulfuron radiolabelled either in the pyridine or pyrimidine ring. Daily dose were approximately 10 mg/kg feed, representing exaggerated dose levels (100–200×) in respect of the anticipated practical dietary burden.

Two metabolic pathways were identified, based on contraction or cleavage of the sulfonylurea bridge, leading to metabolite patterns which are qualitatively similar to rats and plants. Contraction of the sulfonylurea bridge is followed by dealkylation, hydroxylation and/or conjugation reactions. Cleavage of the sulfonylurea bridge yield to pyridine sulfonamide and pyrimidiamine. Elimination of administered rimsulfuron was similarly rapid for the goat and hen. Tissue residue levels for both goat and hen were generally less than 0.3% of the administered dose and there was no evidence of accumulation of rimsulfuron or its metabolites in tissues of any of the species or in milk and eggs.

1.1.3 Residue Definition

Based on metabolism studies which showed a rapid and extensive metabolism of rimsulfuron in the tested crops, the PMRA has determined that only the parent compound should be included in the residue definition for both regulation and risk assessment. This residue definition is consistent with those of the USEPA, the EFSA, the EU and the PSD.

Since livestock metabolism studies conducted at exaggerated dose rates showed no significant concentrations of rimsulfuron or its metabolites in meat, milk, poultry and egg; and since no significant residues are expected to be present in corn or potato products intended for livestock consumption, the PMRA has concluded that there is no need to propose a definition of residue for food of animal origin.

1.2 Analytical Methods

1.2.1 Methods for Residue Analysis of Plants and Plant Products

The PMRA has reviewed analytical methods for determination of residues of the parent compound in plant commodities. The recoveries in corn grain, tomato, processed tomato using HPLC-UV were between 87–93%, 80–98% and 70–100%, respectively. As well, an LC/MS/MS method was reviewed for determination of rimsulfuron residues in corn, potato and tomato with recoveries of 87–98%, 84–101% and 90–108%, respectively. For enforcement purposes, the analytical method reviewed for analysis of rimsulfuron residues in corn grain and corn forage appears to be satisfactory, based on the percentage of recovery and sensitivity of the method.

1.2.2 Methods for Residue Analysis of Food of Animal Origin

An analytical method for food of animal origin is not required (see Section 1.3.3).

1.2.3 Multiresidue Analytical Methods

The multiresidue method for fruits and vegetables of the CFIA does not list rimsulfuron as one of the pesticides that has been evaluated through the MRM protocols. As well, none of the United States Food and Drug Administration multiresidue protocols (A to E) is applicable for the analysis of rimsulfuron. Multiresidue methods are not suitable for the analysis of rimsulfuron.

1.3 Food Residues

1.3.1 Storage Stability

The PMRA has reviewed freezer storage stability studies and concluded that rimsulfuron is stable in corn grain/forage and potato for 24 months when stored frozen at approximately -20°C. The reliability of these results is supported by EFSA review of rimsulfuron storage stability studies. The USEPA states that rimsulfuron residues on tomato are stable for 6 months when stored frozen at approximately -20°C.

1.3.2 Crop Residues

The PMRA has reviewed supervised residue trial studies conducted for corn, potato, tomato and blueberry. As well, the PMRA has also reviewed conclusions from the EFSA report which indicated that the magnitude of rimsulfuron monitored in a total of 51 field studies (24 in corn, 17 in potato and 10 in tomato) identified as reflecting the representative uses (20 g a.i./ha for corn and 27.5 g a.i./ha for tomato) and covering European regions of crop production. All these field trials lead to residues below the LOQ of 0.05 ppm in corn grain, potato and tomato. It is therefore considered that no significant residues of rimsulfuron will be detected on treated corn, potato, tomato and blueberry when treated in accordance with the proposed label directions.

1.3.3 Livestock Residues

Based on the residue data available for the registered uses of rimsulfuron on feed and food crops, there is no expectation that secondary residues will occur in livestock matrices (i.e. meat and meat byproducts, milk and/or eggs) as a result of feeding treated list crop commodities or their by-products when the pesticide is used according to GAP. Consequently, MRLs will not be established in meat, milk and/or eggs at this time. As there is no expectation of dietary exposure to rimsulfuron via livestock commodities, there is no anticipated additional human exposure from consumption of foods of animal origin.

1.3.4 Confined Accumulation in Rotational Crops

The PMRA has concluded that there is no reasonable expectation of residues of rimsulfuron and its metabolites in rotational food crops and feed items when rimsulfuron is applied in accordance with good agricultural practices.

Data from confined rotational crop studies conducted on lettuce, sorghum, soybean, sugar beet, sunflower and wheat showed that rimsulfuron and its metabolites did not accumulate in rotational crops grown in soil treated at a maximum use rate of 35 g a.i./ha, thus at 2.3 times the Canadian maximum rate for corn, potato and tomato. Quantifiable residues (>0.05 ppm) of the main metabolites resulting of contraction of the sulfonylurea bridge and cleavage were observed in soybean and wheat straw only. These chemicals have been identified as degradation products in chemical (hydrolysis, photolysis) and biological (soil, plant, and animal) systems. Total ^{14}C-residue declined steadily from the 30-day aging study to the 10-month aging study.

Appendix VIII Water Monitoring Data

A search for Canadian rimsulfuron water monitoring data revealed that analysis for rimsulfuron is not routinely conducted. Provincial and territorial departments responsible for water quality monitoring were contacted for a summary of existing water monitoring data for the sulfonylureas that are currently under re-evaluation. In addition, requests for existing data were submitted to Environment Canada, the Department of Fisheries and Oceans and the drinking water subcommittee through Health Canada. The information received through these requests were considered in this assessment. American databases were also searched for detections of rimsulfuron in water.

Canadian Data

Data from Canadian water monitoring studies in which rimsulfuron was detected are summarized in Table 1. Four rivers situated in agricultural regions of Quebec that predominantly grow corn (20–36.5% of croped area) and soya (5.6–13.2% of croped area) were sampled three times weekly from the middle of May to the middle of August in the years 2002, 2003, and 2004. Rimsulfuron was detected in 2.6% to 14.3% of the samples analyzed. The maximum concentration of rimsulfuron detected was in one sample at a concentration of 1.0 mg a.i./L (LOD 0.06 µg a.i./L).

The concentrations of mobile pesticides in surface water are directly related to the frequency and timing of monitoring in relation to pesticide application and runoff events. Therefore, timing and frequency of sampling is likely to be the most important factor influencing the concentration detected and the frequency of detections. It should be noted that details on the application of rimsulfuron were not available for the water monitoring study reviewed. For instance, the application rate applied, when the application occurred and weather conditions prior to sampling were not known or reported. Without this information, it is difficult to conclude if non-detects were a result of non-transport or more simply a result of the timing of sampling. In addition, sampling was conducted at regular intervals and, thus, may not have coincided with maximum concentrations resulting from runoff events in the watershed.

US Data

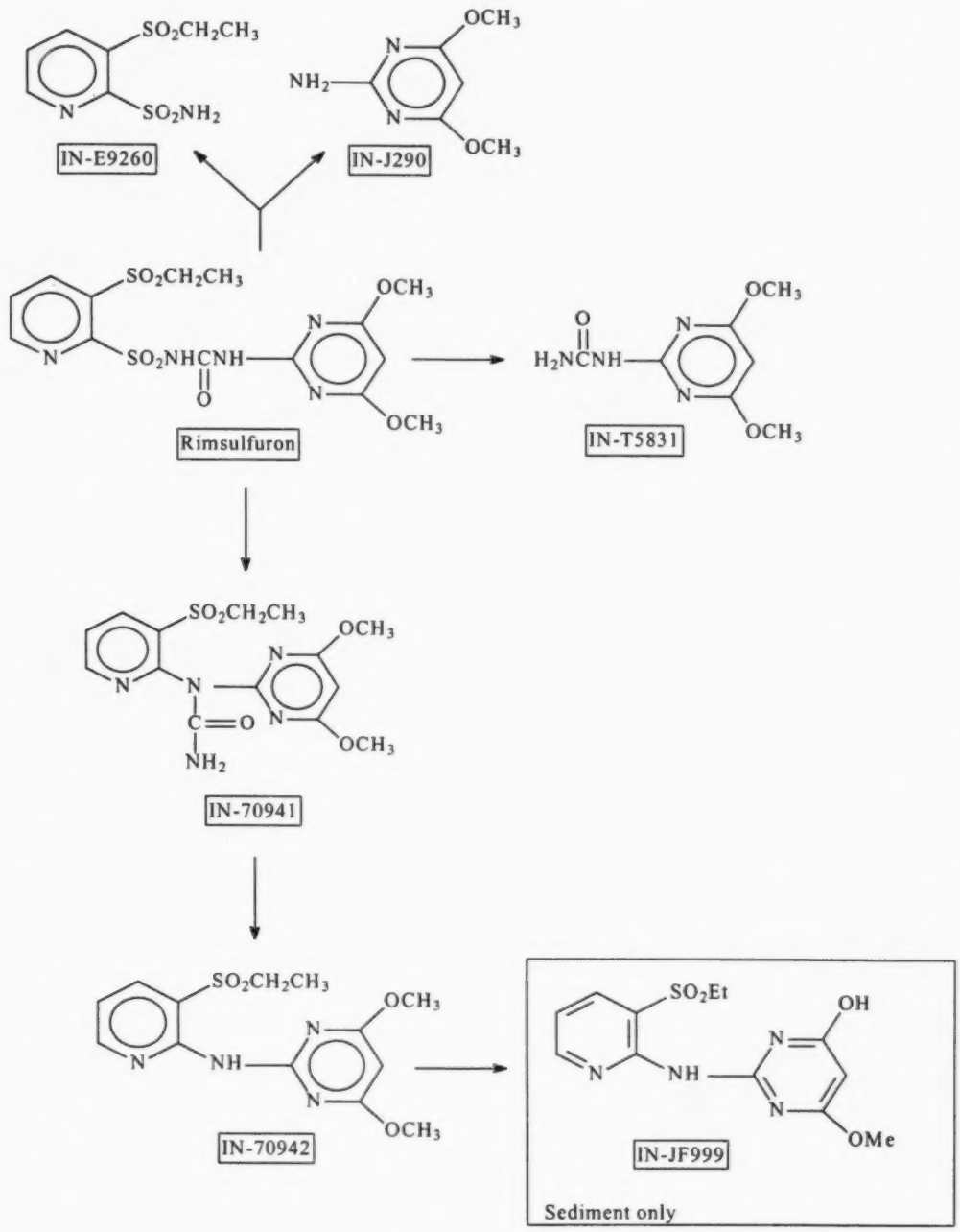
Given the scarcity of data available in Canada for residues of rimsulfuron in water, both the USEPA and the United State Geological Survey databases were searched for detections of rimsulfuron. Rimsulfuron was not included among the analytes that were sampled in either of these databases.

Table 1 Summary of the Monitoring Studies Available

Data Source	DETECTION FREQUENCY						CONCENTRATION PERCENTILES (µg/L) (Analysis includes only data with detections)				
	Location		Min Detection or Detection Limit (µg/L)	# of Systems Tested (or Absolute Number of Samples)	# of Systems or Samples with Detec-tions	% Detection Frequency	Mean Detec-tion	Median Value 50th	95th	Absolute Max	Arithmetic Mean Including Non-detects at ½ LOD
PMRA ID 1295640	Rivière Chibouet	2002	0.01	42	6	14.3	0.09	0.04	0.24	0.26	0.02
		2003	0.06	39	1	2.6				0.07	0.03
		2004	0.06	37	1	2.7				0.03	0.03
	Rivière des Hurons	2002	0.01	42	5	11.9	0.02	0.02	0.03	0.03	0.01
		2003	0.06	39	1	2.6				0.13	0.03
	Rivière Saint-Regis	2002	0.01	40	3	7.5	0.02	0.02	0.03	0.03	0.01
	Rivière Saint-Zephirin	2003	0.06	37	1	2.7				1.00	0.06

Appendix IX Transformation Pathway of Rimsulfuron

Diagram 1: Transformation pathway of rimsulfuron



Appendix X Environmental Fate and Toxicity

Table 1 Environmental Fate of Rimsulfuron, as Technical Active or in Formulation, and its Transformation Products

Study Type	Test Material (% purity)	Study Conditions	Value or Endpoint	Major Transformation Products
Abiotic transformation				
Hydrolysis	Rimsulfuron (>98%)	30 days (pH 5 or 7) or 23 hours (pH 9)	25°C: pH 5 4.5–4.6 days pH 7 7.1–7.3 days pH 9 0.17–0.45 days	IN-70941 IN-70942 IN-E9260
	Rimsulfuron (99%)	30 days	22°C: pH 5 1.5 days pH 7 24.7 days pH 9 0.6 days	
	technical	30 days	20°C: pH 5 1.6 days pH 7 24.2 days pH 9 0.8 days 30°C: pH 5 0.5 days pH 7 4.7 days pH 8 0.9 days 10°C: pH 5 6.0 days pH 7 144 days pH 9 23.8 days	IN-70941 IN-70942 IN-E9260
	Rimsulfuron (99.5%)	150 hours	23°C: pH 6 2.0 days pH 10 instantaneous	IN-70941 IN-70942
	IN-70941 (99.5%)	30 days	25°C: pH 5 144 days pH 7 8 days pH 9 0.08 days	
	IN-70941	Not available	23°C: pH 6 2.5 days	
	IN-70942 (100%)	30 days	25°C: Stable at pH 5, pH 7, and pH 9	
	IN-70942	Not available	23°C: Stable at pH 6 after 150 hours	
	IN-E9260 (92%)	5-9 days	50, 70, and 90°C: Stable pH 4, pH 7, and pH 9	
Phototrans-formation - soil	Rimsulfuron (>97%)	25°C; natural sunlight; 27–34 days; pH 6.7, 1.1% OM	Sandy loam irradiated: 11–12 days dark control: 11–12 days	IN-70941 IN-70942 IN-E9260 IN-J290 IN-T5831
Phototrans-formation - water	Rimsulfuron (>98%)	25°C; natural sunlight; 30 days	irradiated: pH 5 1.1 days pH 7 11.0–12.4 days pH 9 0.4–0.5 days dark control: pH 5 4.7 days pH 7 6.4–6.5 days pH 9 0.3–0.6 days	IN-70941 IN-70942 IN-E9260 IN-J290
	IN-70942 (100%)	25°C; pH 7; xenon lamp (filter > 290 nm); 15 days	irradiated: 1.1 days dark control: stable	

Study Type	Test Material (% purity)	Study Conditions	Value or Endpoint	Major Transformation Products
Biotransformation				
Soil - aerobic	Rimsulfuron (>97.8%)	25°C; dark; 12 months; closed system; pH 6.7, 1.1% OM	Sandy loam: 21 days (75% MWHC)	IN-70941 IN-70942 IN-E9260
	Rimsulfuron (99% purity unlabeled)	20 ± 2°C; up to 100 days; partially closed system; sandy loam (pH 6.7); two loamy sand (pH 5.6–7.0, 2.3% OM)	Sandy loam: 40 days (40% MWHC) Loamy sand: 25–30 days (40% MWHC) 5 days (60% MWHC)	
	Rimsulfuron (99% purity unlabeled)	10 ± 1°C; up to 100 days; partially closed system; pH 5.6, 2.3% OM	Loamy sand: 77 days (40% MWHC)	
	Rimsulfuron (unknown)	20°C; 61 days; open system; pH 6.2, 1.9% OM	Sandy loam: 18 days (75% MWHC)	
	IN-E9260 (99%)	20 ± 2°C; 120 days; closed system; clay (pH 7.9, 1.6% OC); two sandy loam (pH 5.4–5.8, 1.1–1.2% OC)	Sandy loam: 744–969 days (40-50% MWHC) Clay: 252 days (40–50% MWHC)	
	IN-70941 (99%)		Sandy loam: 359–615 days (40-50% MWHC) Clay: 38 days (40–50% MWHC)	
	IN-70942 (99%)		Sandy loam: 116–214 days (40-50% MWHC) Clay: 101 days (40–50% MWHC)	
Soil - anaerobic	Rimsulfuron (>97.8%)	25°C; dark; aerobic pre-incubation 10 days, anaerobic incubation 60 days; pH 6.7, 1.1% OM	Sandy loam: 18 days (75% MWHC)	IN-70941 IN-70942 IN-E9260
	formulation: Titus® (25%)	23°C; 12 days; pH 8.1, 1.1% OM	Sandy loam: 6.9 days (flooded soil)	IN-70941 IN-70942
	IN-70941 (99.5%)	23°C; 30 days; pH 8.1, 1.1% OM	Sandy loam: 3.5–5.0 days (flooded soil)	IN-70942
	IN-70942 (98.2%)	23°C; 30 days; pH 8.1, 1.1% OM	Sandy loam: 8.1–55 days (flooded soil)	
Water - aerobic	Rimsulfuron (>95%)	unfiltered pond water; (pH7.8-8.4); 6 months; 16h light:8h dark; aerated continuously	25°C: 2.0–2.1 days 5°C: 48–59 days	IN-70941 IN-70942

Study Type	Test Material (% purity)	Study Conditions	Value or Endpoint	Major Transformation Products
Water/Sediment-aerobic/anaerobic	Rimsulfuron (>95%)	20°C; 89 days; 12h light: 12h dark; redox in sediment 60–84 mV; water pH 8.6–8.9; sand (pH 6.1, 0.7% OC); clay loam (pH 6.5, 7.4% OC)	Low OM: whole system 5.6 days High OM: whole system 5.2–6.2 days	IN-70941 IN-70942 Unknown A (High OM)
	Rimsulfuron (>95%)	20 ± 2°C; 100 days; dark; redox in sediment -185 to -330mV; water pH 6.7and dissolved organic carbon 8.8–13 µg/mL; sand (pH 5.7, 3.4% OC)	Mills Lawn - Rimsulfuron whole system: 11 days water phase: 7 days sediment phase: 9 days	IN-70941 IN-70942 IN-JF999 (sediment)
			IN-70941 whole system: 28 days water phase: 31 days sediment phase: 45 days	
			IN-70942 whole system: 107 days water phase: 22 days sediment phase: 128 days	
			IN-JF999 sediment phase: 86 days	
Water/Sediment - aerobic/aerobic	Rimsulfuron (>95%)	20 ± 2°C; 100 days; dark; redox in sediment 292–436 mV; water pH 4.3 and dissolved organic carbon 7.6–14.2 µg/mL; clay loam (pH 4.8, 1.6% OC)	Blackiston - Rimsulfuron whole system: 1 days water phase: 1 days sediment phase: 12 days	IN-70941 IN-70942
			IN-70941 whole system: 12 days water phase: 9 days sediment phase: 19 days	
			IN-70942 water phase: 27 days sediment phase: still increasing at study termination (100 days)	
Mobility				
Adsorption/ desorption	Rimsulfuron (>98%)	25 ± 1°C; one 4h equilibrium, two 4h desorption; clay loam (pH 7.7, 2.5% OC); silt loam (pH 5.4, 2.5% OC); two sandy loam (pH 6.5–6.3, 0.6–1.2% OC)	Kd (ml/g) K_{oc} (ml/g) Sandy loam: 0.27–0.35 22.2–59.9 Clay loam: 1.40 56.1 Silt loam: 1.58 63.1	
	IN-E9260 (99%)	20 ± 1°C; one 24h equilibrium, two 24h desorption; clay (pH 7.9, 1.6% OC); three sandy loam (pH 5.4–6.3, 0.5–1.2% OC)	Kd (ml/g) K_{oc} (ml/g) Sandy loam: 0.18–0.24 16–40 Clay: 1.56 97	
	IN-70941 (99%)		Kd (ml/g) K_{oc} (ml/g) Sandy loam: 0.33–0.52 41–66 Clay: 2.21 139	

Study Type	Test Material (% purity)	Study Conditions	Value or Endpoint	Major Transformation Products
	IN-70942 (99%)		Kd (ml/g) K_{oc} (ml/g) Sandy loam: 1.57–4.34 223–362 Clay: 4.96 310	
Thin-layer chromatography	Rimsulfuron - fresh	soil aged 10 days; clay loam (pH 7.7, 2.5% OC); silt loam (pH 5.4, 2.5% OC); two sandy loam (pH 6.5–6.3, 0.6–1.2% OC)	Sandy loam: R_f of 0.71–0.93 Clay loam: R_f of 0.56 Silt loam: R_f of 0.53	
	Rimsulfuron - aged		Sandy loam: R_f of 0.55–0.82 Clay loam: R_f of 0.33–0.48 Silt loam: R_f of 0.34–0.39	
	IN-70941		Sandy loam: R_f of 0.65–0.74 Clay loam: R_f of 0.17 Silt loam: R_f of 0.29	
	IN-70942		Sandy loam: R_f of 0.41–0.56 Clay loam: R_f of 0.18 Silt loam: R_f of 0.07	
Soil column leaching	- fresh formulation + Exell	30 cm deep column; equvalent of 200 mm rainfall over 48 hours; sand (pH 6.1, 0.7% OC); loamy sand (pH 6.3, 2.3% OC); two sandy loam (pH 6.2–6.7, 1.3% OC)	% recovered in leachate as rimsulfuron Sand: 51–60% Sandy loam: nd to 5.8% Sandy loam: 54–61% Loamy sand: 45–50%	IN-70941 in leachate IN-70942 in leachate and soil
	- aged formulation + Exell	pre-incubated 30 days, dark, 40% MWHC, 20°C; 28 cm deep column; equvalent of 200 mm rainfall over 48 hours; pH 6.1, 0.7% OC	% recovered in leachate as rimsulfuron Sand: 3.0–5.7%	IN-70941and IN-70942 in leachate and soil
Volatilization	formulation:DP X-E9636 25 DF	25–28°C; 24 hours; 38–45% relative humidity; laminar air flow 1.3–1.5 m/sec; sand (pH 5.9, 0.7% OC)	Sand: 2.2% loss from soil in 24 h Bean: 0.3% loss from leaves in 24h	
	formulation: DPX-E9636 25 DF + Exell		Sand: No loss from soil in 24h Bean: 3.5% loss from leaves in 24h	
	Rimsulfuron	Atkinson calculation	≤ 10.3% of applied measured as CO_2 Half-life of 0.25 days	

Study Type	Test Material (% purity)	Study Conditions	Value or Endpoint	Major Transformation Products
Field Studies				
Field dissipation	DPX-E9636 25DF (25%)		- No Canadian field trials were available for review. - US field trials conducted in ecoregions relevant to Canada were not acceptable due to insufficient sampling: could not determine DT_{50}s	
	formulation		- Supplemental results for US and European field trials US (Ecoregions 8.2, 8.5, and 11.1): DT_{50}s of 7.9–17.7 days	
	formulation		US (Ecoregion 8.5): DT_{50}s of 5.4–5.9 days	
	Rimsulfuron 25WG (25%) + Trend 90 Titus + Trend		Germany: DT_{50} of 10 days Denmark: DT_{50} of 14 days Spain: DT_{50} of 5.6 days Belgium: DT_{50}s of 14–23 days Belgium: (with organic fertilizers) DT_{50}s of 19–46 days	

Table 2 Environmental Toxicity of Rimsulfuron, as Technical Active or in Formulation, and its Transformation Products

Organism	Study Type	Species	Test Material (% purity)	Endpoint	Value (effect)	Effect of Concern
Terrestrial Species						
Invertebrate	Acute oral	Honeybee (*Apis mellifera*)	Rimsulfuron (99%)	48-h LC_{50} NOEC	> 700 mg a.i./kg diet 1000 mg a.i./kg diet	mortality
			formulation: Rimsulfuron 25 WG	48-h LC_{50} NOEC	> 100 µg a.i./bee 100 µg a.i./bee	mortality
			formulation: Rimsulfuron 25 WG + IN-KG691	48-h LC_{50}	41 µg a.i./bee	mortality
	Acute contact	Earthworm (*Eisenia fetida*)	Rimsulfuron (98.8%)	14-d LC_{50} **NOEC**	> 1000 mg a.i./kg soil **1000 mg a.i./kg soil**	mortality
		Honeybee (*Apis mellifera*)	Rimsulfuron (98.8%)	**48-h LD_{50}** NOEC	**> 100 µg a.i./bee** 100 µg a.i./bee	mortality
		Earthworm (*Eisenia fetida*)	formulation: Rimsulfuron 25WG (250g a.i./kg)	14-d LC_{50} NOEC	> 1000 mg EP/kg soil 1000 mg EP/kg soil	mortality
			formulation: DPX-E9636 25 DF (250g a.i./kg) + Exell	14-d LC_{50} NOEC	> 1000 mg EP/kg soil 1000 mg EP/kg soil	mortality
		Honeybee (*Apis mellifera*)	formulation: Rimsulfuron 25 WG + IN-KG691	48-h LD_{50}	17.8 µg a.i./bee	mortality
		Predatory mite (*Typhlodromus pyri*)	formulation: Rimsulfuron 25 WG 4.4–110 g EP/ha	14-day beneficial capacity	8–9% 0%	mortality fertility
			formulation: Rimsulfuron 25 WG + IN-KG691 4.4–110 g EP/ha	14-day beneficial capacity	3–11% 0%	mortality fertility
		Parasitic wasp (*Aphidius rhopalosiphi*)	formulation: Rimsulfuron 25 WG 150 g EP/ha	48-hour beneficial capacity	14% 1%	mortality parasitation

Organism	Study Type	Species	Test Material (% purity)	Endpoint	Value (effect)	Effect of Concern
		Green lacewing (*Chrysoperla carnea*)	formulation: Rimsulfuron 25 WG 150 g EP/ha	beneficial capacity	4% 22%	mortality fertility
		Staphylinid beetle (*Aleochara bilineata*)	formulation: Rimsulfuron 25 WG 4.4–110 g EP/ha	28-day beneficial capacity	0% 5–22%	mortality parasitation
	Reproduction	Earthworm (*Eisenia fetida*)	IN-70941	8-wk NOEC	0.18 mg TP/kg soil	reproduction
			IN-70942	8-wk NOEC	0.18 mg TP/kg soil	reproduction
			IN-E9260	8-wk NOEC	0.18 mg TP/kg soil	reproduction
Birds	Acute oral	Bobwhite quail (*Colinus virginianus*)	Rimsulfuron (98.8%)	LD_{50} **NOEC**	> 2250 mg a.i./kg bw **2250 mg a.i./kg bw**	mortality
		Mallard duck (*Anas platyrhynchos*)		LD_{50} **NOEC**	> 2000 mg a.i./kg bw **2000 mg a.i./kg bw**	mortality
		Bobwhite quail (*Colinus virginianus*)	formulation: Rimsulfuron 25 DF (25%)	LD_{50} NOEC	> 2250 mg EP/kg bw 1350 mg EP/kg bw	mortality
		Mallard duck (*Anas platyrhynchos*)		LD_{50} NOEC	> 2250 mg EP/kg bw 2250 mg EP/kg bw	mortality
	Dietary	Bobwhite quail (*Colinus virginianus*)	Rimsulfuron (98.8%)	8-d LC_{50} **NOEC**	> 5620 mg a.i./kg diet **5620 mg a.i./kg diet**	mortality
		Mallard duck (*Anas platyrhynchos*)		5-d LC_{50} **NOEC**	> 5620 mg a.i./kg diet **5620 mg a.i./kg diet**	mortality
		Bobwhite quail (*Colinus virginianus*)	formulation: Rimsulfuron 25 DF	8-d LC_{50} NOEC	> 5620 mg EP/kg diet 5620 mg EP/kg diet	mortality
		Mallard duck (*Anas platyrhynchos*)		8-d LC_{50} NOEC	> 5620 mg EP/kg diet 5620 mg EP/kg diet	mortality
	Reproduction	Bobwhite quail (*Colinus virginianus*)	Rimsulfuron (>98.8%)	**NOEC**	**1250 mg a.i./kg diet**	reproduction
		Mallard duck (*Anas platyrhynchos*)		**NOEC**	**1250 mg a.i./kg diet**	reproduction

Organism	Study Type	Species	Test Material (% purity)	Endpoint	Value (effect)	Effect of Concern
Mammals	Acute oral	Mouse	Rimsulfuron (>98%)	LD_{50}	> 5000 mg a.i./kg bw	mortality
		Rat		**LD_{50}**	**> 5000 mg a.i./kg bw**	mortality
	Dietary	Mouse	Rimsulfuron (97.5%)	90-d NOAEL	2.28 mg/kg bw/day (1500 mg a.i./kg diet)	growth
		Rat		**90-d NOAEL**	**3.35 mg/kg bw/day (50 mg a.i./kg diet)**	growth
	Reproduc-tion (2-generation)	Rat	Rimsulfuron (98.8%)	**NOAEL**	**165 mg/kg bw/day (3000 mg a.i./kg diet)**	parental growth
Plants	Seedling emergence	Canola	Rimsulfuron (98.8%)	**14-d EC_{25}** 14-d EC_{50} NOEC	**0.15 g a.i./ha** 0.69 g a.i./ha <0.27 g a.i./ha	growth
		11 monocot + 6 dicot species	IN-70941	NOEC	400 g TP/ha	growth
			IN-70942	NOEC	400 g TP/ha	growth
			IN-E9260	NOEC	400 g TP/ha	growth
	Vegetative vigor	Sorghum	formulation: Rimsulfuron (98.8%) + Valent X-77 Spreader (4%)	**21-d EC_{25}** 21-d EC_{50} NOEC	**0.08 g a.i./ha** 0.17 g a.i./ha 0.07 g a.i./ha	growth
			formulation: DPX-E9636-136 (25%)	21-d EC_{25} 21-d EC_{50}	3.24 g EP/ha 4.89 g EP/ha	growth
		11 monocot + 6 dicot species	IN-70941	NOEC	400 g TP/ha	growth
			IN-70942	NOEC	400 g TP/ha	growth
			IN-E9260	NOEC	400 g TP/ha	growth

Organism	Study Type	Species	Test Material (% purity)	Endpoint	Value (effect)	Effect of Concern
Freshwater Species						
Invertebrate	Acute	*Daphnia carinata*	technical	**48-h EC_{50}**	**> 100 mg a.i./L**	immobility
		Daphnia magna	Rimsulfuron (98.8%)	48-h EC_{50} 48-h NOEC	> 360 mg a.i./L 190 mg a.i./L	immobility
				48-h EC_{50} 48-h NOEC	~ 1000 mg a.i./L 800 mg a.i./L	immobility
		Daphnia carinata	formulation: Rimsulfuron 25DF (25%)	48-h EC_{50}	> 100 mg EP/L	immobility
		Daphnia magna	formulation: DPX-E9636-48 (250 g/kg)	48-h EC_{50} 48-h NOEC	1.0 mg EP/L 0.63 mg EP/L	immobility
			formulation: IN-E9636-37 (25%)	48-h EC_{50} 48-h NOEC	> 1000 mg EP/L 1000 mg EP/L	immobility
			IN-70941 (97.8%)	48-h EC_{50} 48-h NOEC	95 mg TP/L 46.1 mg TP/L	immobility
			IN-70942 (98.8%)	48-h EC_{50} 48-h NOEC	178 mg TP/L 100 mg TP/L	immobility
			IN-E9260	48-h EC_{50} 48-h NOEC	184 mg TP/L 25.9 mg TP/L	immobility
	Chronic	*Daphnia magna*	Rimsulfuron (98.8%)	21-d LOEC 21-d NOEC	50 mg a.i./L 1 mg a.i./L	reproduction and growth
			technical	21-d EC_{50} 21-d LOEC **21-d NOEC**	450 mg a.i./L 38 mg a.i./L **0.82 mg a.i./L**	immobility reproduction and growth
			formulation: IN-E9636-37 (25%)	21-d EC_{50} 21-d LOEC 21-d NOEC	680 mg EP/L 10 mg EP/L 4.0 mg EP/L	immobility

Organism	Study Type	Species	Test Material (% purity)	Endpoint	Value (effect)	Effect of Concern
Fish	Acute	Bluegill sunfish (*Lepomis macrochirus*)	Rimsulfuron (> 98%)	96-h LC_{50} 96-h NOEC	> 390 mg a.i./L 390 mg a.i./L	mortality
		Rainbow trout (*Oncorhynchus mykiss*)		96-h LC_{50} 96-h NOEC	> 390 mg a.i./L 390 mg a.i./L	mortality
		Common carp (*Cyprinus carpio*)		96-h LC_{50} 96-h NOEC	> 900 mg a.i./L 900 mg a.i./L	mortality
				96-h LC_{50} 96-h NOEC	**> 100 mg a.i./L** 100 mg a.i./L	mortality
		Bluegill sunfish (*Lepomis macrochirus*)	formulation: IN E9636-37 (25%)	96-h LC_{50} 96-h NOEC	> 1000 mg EP/L 594 mg EP/L	mortality
		Rainbow trout (*Oncorhynchus mykiss*)		96-h LC_{50} 96-h NOEC	> 1000 mg EP/L 214 mg EP/L	mortality lethargic swimming
		Common carp (*Cyprinus carpio*)	formulation: Rimsulfuron 25DF (25 g/kg)	96-h LC_{50}	> 100 mg EP/L	mortality
		Rainbow trout (*Oncorhynchus mykiss*)	IN-70941	96-h LC_{50} 96-h NOEC	> 110 mg TP/L 110 mg TP/L	mortality
			IN-70942	96-h LC_{50} 96-h NOEC	> 180 mg TP/L 34 mg TP/L	mortality sublethal effects
			IN- E9260	96-h LC_{50} 96-h NOEC	> 314 mg TP/L 314 mg TP/L	mortality
	Chronic	Rainbow trout (*Oncorhynchus mykiss*)	Rimsulfuron (98.8%)	21-d EC_{50} 21-d LOEC **21-d NOEC**	390 mg a.i./L 250 mg a.i./L **125 mg a.i./L**	mortality
			formulation: Rimsulfuron 25DF (25%)	21-d EC_{50} 21-d NOEC	720 mg EP/L 130 mg EP/L	sublethal effects
	Early life-stage	Rainbow trout (*Oncorhynchus mykiss*)	Rimsulfuron (99%)	90-d LOEC **90-d NOEC**	250 mg a.i./L **125 mg a.i./L**	growth

Organism	Study Type	Species	Test Material (% purity)	Endpoint	Value (effect)	Effect of Concern
Algae	Acute	Green Algae (*Selenastrum capricornutum*)	Rimsulfuron (> 97%)	**72-h EC_{50}** 72-h NOEC 120-h EC_{50}	**1.2 mg a.i./L** 0.625 mg a.i./L 1.6 mg a.i./L	biomass
				120-h EC_{50} 120-h NOEC	> 0.029 mg a.i./L 0.029 mg a.i./L	biomass
		Blue-green algae (*Anabaena flos-aquae*)		96-h EC_{50} 96-h NOEC	1.9 mg a.i./L 0.45 mg a.i./L	biomass cell density
				120-h EC_{50} 120-h NOEC	> 0.035 mg a.i./L 0.035 mg a.i./L	biomass
		Diatom (*Navicula pelliculosa*)		120-h EC_{50} 120-h NOEC	> 0.035 mg a.i./L < 0.035 mg a.i./L	biomass, cell density
				120-h EC_{50} 120-h NOEC	> 0.109 mg a.i./L 0.109 mg a.i./L	biomass
		Green Algae (*Selenastrum capricornutum*)	formulation: Rimsulfuron 25DF (255 g/kg)	72-h EC_{50} 72-h NOEC	0.8 mg EP/L 0.125 mg EP/L	cell density
		Blue-green algae (*Anabaena flos-aquae*)	formulation: Rimsulfuron 25DF (25%)	96-h EC_{50} 96-h NOEC	1.5 mg EP/L 1.0 mg EP/L	biomass
		Green Algae (*Selenastrum capricornutum*)	formulation: Rimsulfuron 25DF (5.4%) + IN-KG691	72-h EC_{50} 72-h NOEC	3.3 mg EP/L 0.95 mg EP/L	cell density, biomass
		Blue-green algae (*Anabaena flos-aquae*)		96-h EC_{50} 96-h NOEC	25.8 mg EP/L 13.9 mg EP/L	cell density
		Green Algae (*Selenastrum capricornutum*)	IN-70941	72-h EC_{50} 72-h NOEC	> 8.9 mg TP/L 8.9 mg TP/L	biomass
			IN-70942	72-h EC_{50} 72-h NOEC	> 10 mg TP/L 10 mg TP/L	biomass
				72-h EC_{50} 72-h NOEC	> 16 mg TP/L 4 mg TP/L	biomass
			IN-E9260	72-h EC_{50} 72-h NOEC	> 100 mg TP/L 100 mg TP/L	biomass

Organism	Study Type	Species	Test Material (% purity)	Endpoint	Value (effect)	Effect of Concern
Plants	Acute	Duckweed (*Lemna gibba*)	Rimsulfuron (98.8%)	7-d EC_{50} 14-d EC_{50} 14-d NOEC	0.018 mg a.i./L 0.0116 - 0.027 mg a.i./L* 0.00009 - 0.0009 mg a.i./L*	frond density, biomass
				14-d EC_{50} 14-d NOEC	**0.0046 mg a.i./L** 0.001 mg a.i./L	frond density, biomass
			formulation: Rimsulfuron 25WG (25%)	14-d EC_{50} 14-d NOEC	0.0315 mg EP/L 0.002 mg EP/L	frond density
			formulation: Rimsulfuron 25WG (5.4%) + IN-KG691	14-d EC_{50} 14-d NOEC	0.16 mg EP/L 0.0192 mg EP/L	frond density
			IN-70942	14-d EC_{50} 14-d NOEC	> 0.0175 mg TP/L 0.0175 mg TP/L	frond density, biomass
Marine and Estuarine Organisms						
Invertebrate	Acute	Mysid shrimp (*Mysidopsis bahia*)	Rimsulfuron (99%)	**96-h LC_{50}** 96-h NOEC	**> 112 mg a.i./L** < 112 mg a.i./L	mortality
		Eastern oyster (*Crassotrea virginica*)		96-h EC_{50} 96-h NOEC	> 121 mg a.i./L < 121 mg a.i./L	shell deposition
Fish	Acute	Sheepshead minnow (*Cyprinodon variegatus*)	Rimsulfuron (98.8%)	**96-h LC_{50}** 96-h NOEC	**> 110 mg a.i./L** 110 mg a.i./L	mortality
Algae	Acute	Diatom (*Skeletonema costatum*)	Rimsulfuron (98.8%)	**120-h EC_{50}** 120-h NOEC	**> 0.048 mg a.i./L** 0.048 mg a.i./L	cell density

* Same data were interpreted differently by four countries

Bolded text was used in the PMRA risk assessment

EP = end-use product; TP = transformation product.

Table 3a Summary of Screening Level Risk Assessment of Rimsulfuron to Terrestrial Organisms

Organism	Exposure	Endpoint Reported	Use Rate (g a.i./ha)	EEC	RQ
Invertebrates					
Earthworm	Acute	NOEC = 1000 mg a.i./kg soil	12.6	5.6×0^{-3} mg a.i./kg soil	6.0×10^{-6}
			15	6.7×10^{-3} mg a.i./kg soil	7.0×10^{-6}
Honeybee	Acute contact	LD_{50} > 100 µg a.i./bee (112 kg a.i./ha)	12.6	1.26×10^{-2} kg a.i./ha	1.1×10^{-4}
			15	1.5×10^{-2} kg a.i./ha	1.3×10^{-4}
Birds					
Mallard	Dietary	NOEC = 5620 mg a.i./kg diet	12.6	0.42 mg a.i./kg diet	7.5×10^{-5}
			15	0.51 mg a.i./kg diet	9.7×10^{-5}
	Reproduction	NOEC = 1250 mg a.i./kg diet	12.6	0.42 mg a.i./kg diet	3.4×10^{-4}
			15	0.51 mg a.i./kg diet	4.1×10^{-4}
Bobwhite quail	Dietary	NOEC = 5620 mg a.i./kg diet	12.6	2.19 mg a.i./kg diet	3.9×10^{-4}
			15	2.63 mg a.i./kg diet	4.7×10^{-4}
	Reproduction	NOEC = 1250 mg a.i./kg diet	12.6	2.19 mg a.i./kg diet	1.7×10^{-3}
			15	2.63 mg a.i./kg diet	2.1×10^{-3}
American Robin	Dietary	NOEC = 1487 mg a.i./kg diet	12.6	1.21 mg a.i./kg diet	8.1×10^{-4}
			15	1.45 mg a.i./kg diet	9.7×10^{-4}
Field Sparrow	Dietary	NOEC = 3031 mg a.i./kg diet	12.6	1.48 mg a.i./kg diet	4.9×10^{-4}
			15	1.76 mg a.i./kg diet	5.8×10^{-4}
Mammals					
Rat	Dietary	NOAEL = 50 mg a.i./kg diet	12.6	6.31 mg a.i./kg diet	0.13
			15	7.57 mg a.i./kg diet	0.15
	Reproduction	NOAEL = 3000 mg a.i./kg diet	12.6	6.31 mg a.i./kg diet	2.1×10^{-3}
			15	7.57 mg a.i./kg diet	2.5×10^{-3}
Plants					
Plants	Seedling emergence (canola)	EC_{25}: 0.15 g a.i./ha	12.6	12.6 g a.i./ha	**84**
			15	15 g a.i./ha	**100**
	Vegetative vigor (sorghum)	EC_{25}: 0.08 g a.i./ha	12.6	12.6 g a.i./ha	**157**
			15	15 g a.i./ha	**187**

Bolded values indicates an exceedance of the level of concern (RQ = 1)

Table 3b Summary of Screening Level Risk Assessment of Rimsulfuron Transformation Products to Terrestrial Organisms

Organism	Exposure	Endpoint Reported	Use Rate (g a.i./ha)	EEC*	RQ
Earthworm	Reproduction	**IN-70941**			
		NOEC = 0.18 mg TP/kg soil	12.6	5.6×10^{-3} mg a.i./kg soil	0.031
			15	6.7×10^{-3} mg a.i./kg soil	0.037
		IN-70942			
		NOEC = 0.18 mg TP/kg soil	12.6	5.6×10^{-3} mg a.i./kg soil	0.031
			15	6.7×10^{-3} mg a.i./kg soil	0.037
		IN-E9260			
		NOEC = 0.18 mg TP/kg soil	12.6	5.6×10^{-3} mg a.i./kg soil	0.031
			15	6.7×10^{-3} mg a.i./kg soil	0.037

* Assumption that the EECs for transformation products are the same as those for the parent compound rimsulfuron

Bolded values indicates an exceedance of the level of concern (RQ = 1)

Table 4 Refined Risk Assessment for Rimsulfuron to Terrestrial Plants

Organism	Exposure	EC_{25}	Use Rate (g a.i./ha)	% Application Rate to Reach EC_{25}	Drift EEC*	RQ
Plants	Seedling emergence (canola)	0.15 g a.i./ha	12.6	1.2	0.76 g a.i./ha	**5.1**
			15	1	0.90 g a.i./ha	**6**
	Vegetative vigor (sorghum)	0.08 g a.i./ha	12.6	0.6	0.76 g a.i./ha	**9.5**
			15	0.5	0.90 g a.i./ha	**11.25**

* Based on drift of 6% for a default droplet size of medium (herbicides).

Bolded values indicates an exceedance of the level of concern (RQ = 1)

Table 5a Summary of Screening Level Risk Assessment of Rimsulfuron to Aquatic Organisms

Organism	Exposure	Species	Endpoint reported (mg a.i./L)	Endpoint for RA* (mg a.i./L)	Use Rate (g a.i./ha)	EEC** (mg a.i./L)	RQ
Freshwater Species							
Invertebrate	Acute	*D. carinata*	$EC_{50} > 100$	50	12.6	1.57×10^{-3}	3.1×10^{-5}
					15	1.87×10^{-3}	3.7×10^{-5}
	Chronic	*D. magna*	NOEC = 0.82	0.82	12.6	1.57×10^{-3}	1.9×10^{-3}
					15	1.87×10^{-3}	1.9×10^{-3}
Fish	Acute	Common carp	$LC_{50} > 100$	10	12.6	1.57×10^{-3}	1.6×10^{-4}
					15	1.87×10^{-3}	1.9×10^{-4}
	Chronic	Rainbow trout	NOEC = 125	125	12.6	1.57×10^{-3}	1.3×10^{-5}
					15	1.87×10^{-3}	1.5×10^{-5}
Plant	Acute	Green algae	$EC_{50} = 1.2$	0.6	12.6	1.57×10^{-3}	2.6×10^{-3}
					15	1.87×10^{-3}	2.6×10^{-3}
	Acute	Duckweed	$EC_{50} = 0.001$	0.0005	12.6	1.57×10^{-3}	**3.14**
					15	1.87×10^{-3}	**3.74**
Amphibian	Acute	Common carp (surrogate)	$LC_{50} > 100$	10	12.6	8.4×10^{-3}	8.4×10^{-4}
					15	1.0×10^{-2}	1.0×10^{-3}
	Chronic	Fish Early Life Cycle (surrogate)	NOEC = 125	125	12.6	8.4×10^{-3}	6.7×10^{-5}
					15	1.0×10^{-2}	8.0×10^{-5}
Estuarine and Marine Species							
Invertebrate	Acute	Mysid shrimp	$LC_{50} > 112$	56	12.6	1.57×10^{-3}	2.8×10^{-5}
					15	1.87×10^{-3}	3.4×10^{-5}
Fish	Acute	Sheepshead minnow	$LC_{50} > 110$	11	12.6	1.57×10^{-3}	1.4×10^{-4}
					15	1.87×10^{-3}	1.7×10^{-4}
Plant	Acute	Diatom	$EC_{50} > 0.048$	0.024	12.6	1.57×10^{-3}	6.6×10^{-2}
					15	1.87×10^{-3}	7.8×10^{-2}

* Endpoints used in the acute exposure risk assessment (RA) are derived by dividing the EC_{50} or LC_{50} from the appropriate laboratory study by a factor of two (2) for aquatic invertebrates and plants, and by a factor of ten (10) for fish and amphibians.

** EEC based on a 15 cm water body depth for amphibians and a 80 cm water depth for all other aquatic organisms.

Bolded values indicates an exceedance of the level of concern (RQ = 1).

Table 5b Summary of Screening Level Risk Assessment of Rimsulfuron Transformation Products to Aquatic Organisms

Organism	Exposure	Species	Endpoint Reported (mg a.i./L)	Endpoint for RA* (mg a.i./L)	Use Rate (g a.i./ha)	EEC** (mg a.i./L)	RQ
IN-70941							
Invertebrate	Acute	*D. magna*	EC_{50} = 95	47.5	12.6	1.57×10^{-3}	3.3×10^{-5}
					15	1.87×10^{-3}	3.9×10^{-5}
Fish	Acute	Rainbow trout	LC_{50} > 110	11	12.6	1.57×10^{-3}	1.4×10^{-4}
					15	1.87×10^{-3}	1.7×10^{-4}
Plant	Acute	Green algae	EC_{50} > 8.9	4.45	12.6	1.57×10^{-3}	3.5×10^{-4}
					15	1.87×10^{-3}	4.2×10^{-4}
Amphibian	Acute	Rainbow trout (surrogate)	LC_{50} > 110	11	12.6	8.4×10^{-3}	7.6×10^{-4}
					15	1.0×10^{-2}	9.1×10^{-4}
IN-70942							
Invertebrate	Acute	*D. magna*	EC_{50} = 178	89	12.6	1.57×10^{-3}	1.8×10^{-5}
					15	1.87×10^{-3}	2.1×10^{-5}
Fish	Acute	Rainbow trout	LC_{50} > 180	18	12.6	1.57×10^{-3}	8.7×10^{-5}
					15	1.87×10^{-3}	1.0×10^{-4}
Plant	Acute	Green algae	EC_{50} > 10	5	12.6	1.57×10^{-3}	3.1×10^{-4}
					15	1.87×10^{-3}	3.7×10^{-4}
	Acute	Duckweed	EC_{50} > 0.00875	0.00875	12.6	1.57×10^{-3}	0.18
					15	1.87×10^{-3}	0.21
Amphibian	Acute	Rainbow trout (surrogate)	LC_{50} > 180	18	12.6	8.4×10^{-3}	4.7×10^{-4}
					15	1.0×10^{-2}	5.5×10^{-4}
IN-E9260							
Invertebrate	Acute	*D. magna*	EC_{50} = 184	92	12.6	1.57×10^{-3}	1.7×10^{-5}
					15	1.87×10^{-3}	2.0×10^{-5}
Fish	Acute	Rainbow trout	LC_{50} > 314	31.4	12.6	1.57×10^{-3}	5.0×10^{-5}
					15	1.87×10^{-3}	6.0×10^{-5}
Plant	Acute	Green algae	EC_{50} > 100	50	12.6	1.57×10^{-3}	3.1×10^{-5}
					15	1.87×10^{-3}	3.7×10^{-5}
Amphibian	Acute	Rainbow trout (surrogate)	LC_{50} > 314	31.4	12.6	8.4×10^{-3}	2.7×10^{-4}
					15	1.0×10^{-2}	3.2×10^{-4}

* Endpoints used in the acute exposure risk assessment (RA) are derived by dividing the EC_{50} or LC_{50} from the appropriate laboratory study by a factor of two (2) for aquatic invertebrates and plants, and by a factor of ten (10) for fish and amphibians.

** EEC based on those for rimsulfuron at a 15 cm water body depth for amphibians and a 80 cm water depth for all other aquatic organisms.

Bolded values indicates an exceedance of the level of concern (RQ = 1).

Table 6 Refined Risk Assessment for Rimsulfuron to Freshwater Vascular Plants (*Lemna gibba*)

Risk from Drift							
Organism	**Exposure**	**Species**	**Endpoint Reported (mg a.i./L)**	**Endpoint for RA* (mg a.i./L)**	**Use Rate (g a.i./ha)**	**EEC** (mg a.i./L)**	**RQ**
Plants	Acute	Duckweed	EC_{50} = 0.001	0.0005	12.6	9.45×10^{-5}	0.19
					15	0.00187	0.22
Risk from Runoff							
Organism	**Exposure**	**Species**	**Endpoint Reported (mg a.i./L)**	**Endpoint for RA* (mg a.i./L)**	**Modelling Period**	**EEC (mg a.i./L)**	**RQ**
Plants	Acute	Duckweed	EC_{50} = 0.001	0.0005	21-d average	3.47×10^{-4}	0.69
					Peak value	7.52×10^{-4}	**1.5**

* Endpoints used in the risk assessment (RA) are derived by dividing the EC_{50} from the appropriate laboratory study by a factor of two (2) for aquatic plants.

** Based on drift of 6% for a default droplet size of medium (herbicides).

Runoff EECs were modelled using PRZM/EXAMS.

EECs are based on a 80 cm water depth for aquaticplants.

Bolded values indicates an exceedance of the level of concern (RQ = 1).

Appendix XI Label Amendments for Commercial Class Products Containing Rimsulfuron

Canadian commercial end-use product labels must be amended to include the following statements to further protect workers and the environment.

FOR ALL FORMULATIONS:

Add to **DIRECTIONS FOR USE:**

- Do not re-enter treated fields until 12 hours after application.
- Apply only when the potential for drift to areas of human habitation or areas of human activity (houses, cottages, schools and recreational areas) is minimal. Take into consideration wind speed, wind direction, temperature, application equipment and sprayer settings.
- DO NOT apply this product directly to freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs, ditches and wetlands), estuaries or marine habitats.
- DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.

Field sprayer application:

- **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty.
- **DO NOT** apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) medium classification.
- **DO NOT** apply by air.

Buffer zones:

The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive terrestrial habitats (such as grasslands, forested areas, shelter belts, woodlots, hedgerows, rangelands, riparian areas and shrublands), sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands) and estuarine/marine habitats.

Method of application	Buffer Zones (metres) Required for the Protection of:		
	Terrestrial Habitat	Aquatic habitats of water depths:	
		< 1 m	> 1 m
Field sprayer*	5	1	1

* For field sprayer application, buffer zones can be reduced with the use of drift reducing spray shields. When using a spray boom fitted with a full shield (shroud, curtain) that extends to the crop canopy or ground, the labelled buffer zone can be reduced by 70%. When using a spray boom where individual nozzles are fitted with cone-shaped shields that are no more than 30 cm above the crop canopy or ground, the labelled buffer zone can be reduced by 30%.

When a tank mixture is used, consult the labels of the tank-mix partners and observe the largest (most restrictive) buffer zone of the products involved in the tank mixture.

Add to **PRECAUTIONS:**

- Mixers, loaders and applicators must wear a long-sleeved shirt, long pants, and chemical-resistant gloves (gloves not required for groundboom sprayers).

Add to **ENVIRONMENTAL HAZARDS:**

- TOXIC to non-target terrestrial plants. Observe buffer zones specified under DIRECTIONS FOR USE.
- TOXIC to aquatic organisms. Observe buffer zones specified under DIRECTIONS FOR USE.
- The use of this chemical may result in contamination of groundwater particularly in areas where soils are permeable (e.g. sandy soil) and/or the depth to the water table is shallow.
- To reduce runoff from treated areas into aquatic habitats avoid application to areas with a moderate to steep slope, compacted soil, or clay.

  Avoid application when heavy rain is forecast.

  Contamination of aquatic areas as a result of runoff may be reduced by including a vegetative strip between the treated area and the edge of the water body.

Add to **STORAGE:**

- To prevent contamination store this product away from food or feed.

FOR FORMULATIONS USING CONVENTIONAL PACKAGING (Not Water Soluble Bags):

Add to **DISPOSAL:**

Disposal of Container:

- DO NOT reuse this container for any purpose. This is a recyclable container, and is to be disposed of at a container collection site. Contact your local distributor/dealer or municipality for the location of the nearest collection site. Before taking the container to the collection site:
  - Triple- or pressure-rinse the empty container. Add the rinsings to the spray mixture in the tank.
  - Make the empty, rinsed container unsuitable for further use.

    If there is no container collection site in your area, dispose of the container in accordance with provincial requirements.

    For information on disposal of unused, unwanted product, contact the manufacturer or the provincial regulatory agency. Contact the manufacturer and the provincial regulatory agency in case of a spill, and for clean-up of spills.

FOR WETTABLE GRANULE FORMULATIONS:

Add to **DIRECTIONS FOR USE:**

- Rimsulfuron can be formulated as wettable granules sealed within a water-soluble package (WSP). Drop intact WSP directly into spray tank. The WSP and pesticide will dissolve readily in water.
- Do not allow the WSP to become wet prior to use. Do not handle individual WSP with wet hands or wet gloves as this may cause breakage. Do not remove WSP from over-wrap container except for immediate use.
- Do not open water-soluble bags or attempt to remove the contents from them. The contents are not designed to be re-measured or subdivided.
- Do not use opened or punctured WSP.
- If broken WSP is found when the over-wrap bag is opened, avoid contact with, and inhalation of the product. Handle with chemical-resistant gloves and dispose of broken WSP according to the DISPOSAL section.

Appendix XII Supplemental Maximum Residue Limit Information—International Situation and Trade Implications

Rimsulfuron residues resulting from Canadian label uses on blueberry and tomato are covered by B.15.002(1) of the Food and Drug Regulations, while general regulation B.15.002(1) applies to all foods where a specific MRL has not been established for corn and potato. However, changes to this general MRL may be implemented in the future, as indicated in Discussion Document DIS2003-01, *Revocation of the 0.1 ppm General Maximum Residue Limit for Food Pesticide Residues [Regulation B.15.002(1)]*.

Effective 1 August 2007, the USEPA has established new tolerances for residues of rimsulfuron in or on almond hulls, citrus group, fruit pome, fruit stone, grape, nut tree and pistachio. These tolerances are presented below.

Table 1 Comparison between MRLs in Canada and in Other Jurisdictions for Rimsulfuron

Commodity	MRL or Tolerance (ppm)		
	Canada[1]	United States[2]	Codex[3]
Blueberry	0.05	None	None
Corn	0.1	0.1	None
Potato	0.1	0.1	None
Tomato	0.05	0.05	None
Almond hull	0.1	0.09	None
Citrus group	0.1	0.01	None
Fruit pome	0.1	0.01	None
Fruit stone	0.1	0.01	None
Grape	0.1	0.01	None
Nut tree	0.1	0.01	None
Pistachio	0.1	0.01	None

Notes

1 By virtue of subsection B.15.002(1) of the Food and Drug Regulations, the MRL of foods for which MRLs have not specifically been established is 0.1 ppm.

2 As per Title 40 Part 180.478 of the United States Code of Federal Regulations. See also http://www.access.gpo.gov/nara/cfr/waisidx_01/40cfr180_01.html

3 Codex is an international organization under the auspices of the United Nations that develops international food standards, including MRLs.

Table 2 Residue Definition in Canada and Other Jurisdictions

Jurisdiction	Residue Definition
Canada	*N*-[[(4,6-dimethoxy-2-pyrimidinyl)amino]carbonyl]-3-(ethylsulfonyl)-2-pyridinesulfonamide
United States	N-((4,6-dimethoxypyrimidin-2-yl)aminocarbonyl)-3- (ethylsulfonyl)-2-pyridinesulfonamide
Codex (JMPR)	None